United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 739-R-08-001
March 2008

Reregistration Eligibility Decision for Organic Esters of Phosphoric Acid (Case 4122)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the antimicrobial organic esters of phosphoric acid. The enclosed Reregistration Eligibility Decision (RED) document was approved on March 31, 2006.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for organic esters of phosphoric acid and its associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for organic esters of phosphoric acid are available to the public on the U.S. Federal Government website www.regulations.gov. The docket is EPA-HQ-OPP-2007-1166.

The organic esters of phosphoric acid RED was developed through EPA's public participation process, published in the Federal Register on September 10, 2004, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the organic esters of phosphoric acid risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational, residential and ecological risks posed by exposure to organic esters of phosphoric acid alone. This document also identifies both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90 days

from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that organic esters of phosphoric acid will be eligible for reregistration provided that all the conditions identified in this document are satisfied. Sections IV and V of this RED document describe the necessary labeling amendments for end-use products and data requirements. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that will accompany this DCI.

If you have questions on this document or the label changes relevant to this reregistration decision, please contact the Chemical Review Manager, Heather Garvie, at (703) 308-0034. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Marshall Swindell at (703) 308-6341.

Sincerely,

Frank T. Sanders
Director, Antimicrobials Division

REREGISTRATION ELIGIBILITY
DECISION
for
Organic Esters of Phosphoric Acid
List D
CASE 4122

Approved By:

Frank T. Sanders
Director, Antimicrobials Division
March 31, 2008

Attachment

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GLOSSARY OF TERMS AND ABBREVIATIONS

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for organic esters of phosphoric acid and is issuing its risk management decision. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of organic esters of phosphoric acid that pose risks of concern. As a result of this review, EPA has determined that organic esters of phosphoric acid containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

This document presents the Agency's revised human health and ecological risk assessments and the Reregistration Eligibility Decision (RED) for organic esters of phosphoric acid. The organic esters of phosphoric acid case consists of three PC codes: 111286, 129079, and 129080. The PC codes that make up the case are used only in conjunction with each other. There are currently two registered products and no pending registrations. There are no inert uses for organic esters of phosphoric acid. The first product containing organic esters of phosphoric acid was registered in February, 1982. For a list of the current products, please see Appendix A.

Organic esters of phosphoric acid act as fungicides, disinfectants, bacteriostats and microbicides/microbistats. They are used as materials preservatives in carpet backings; epoxy flooring and tiles; vinyl products including wall coverings, car tops, awnings, tarpaulins, tents, sails, drapes, shower curtains, cubicle curtains, and film; paints, textiles (clothing), plastic furniture; polymeric laminates; polymer concrete; water, oil and solvent based paints, stains and other coating systems used on interior and exterior surfaces, machinery and equipment including heating, ventilating and air conditioning systems; molded polymeric and polymer concrete bath tubs, showers and bathroom sinks, countertops and accessories; various molded polymer and polymer concrete products for general household, industrial, commercial and healthcare use; natural and synthetic polymeric sealants, adhesives and caulking compounds; textile and vinyl upholstery, mattresses, mattress ticking and mattress covers; and air filters to be used in furnaces, air conditioners, air purification devices, automobiles and re-circulating air handling systems. The active ingredient is also used as a materials preservative in carpet and floor maintenance products such as shampoos, cleaners and spot removers.

The Agency has determined that analysis of the potential need for a special hazard-based safety factor under the FQPA is not needed at this time. The Agency does not anticipate dietary or drinking water exposures based on the registered use patterns and there are no tolerances or tolerance exemptions for the use of organic esters of phosphoric acid as an active ingredient. Therefore, an FQPA hazard analysis is not necessary at this time.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of organic esters of phosphoric acid. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for organic esters of phosphoric acid referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-1166).

This document consists of six sections. Section I is the Introduction. Section II provides a chemical overview, a profile of the use and usage of organic esters of phosphoric acid and its regulatory history. Section III, Summary of Organic Esters of Phosphoric Acid Risk Assessments, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

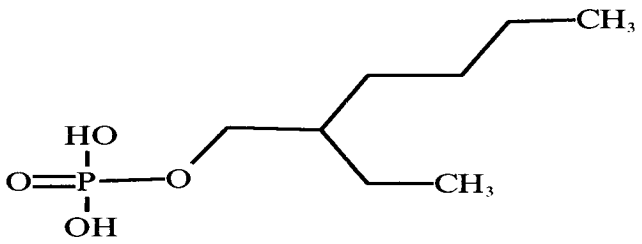
The organic esters of phosphoric acid case consists of three PC codes: 111286, 129079, and 129080. There are two active products and no inert uses. There are no pending registrations. The first product containing phosphoric acid was registered February, 1982. The PC codes that make up the phosphoric acid case are used only in conjunction with each other.

Organic esters of phosphoric acid act as fungicides, disinfectants, bacteriostats and microbicides/microbistats. Their main uses are as a materials preservatives in carpet backings, vinyl and polymer products, carpet/floor cleaners, paint, textiles and mattresses. There are no inert products containing organic esters of phosphoric acid.

B. Chemical Identification

Common Name:	Organic esters of phosphoric acid
Chemical Name:	Phosphoric acid, mono(2-ethylhexyl) ester, Phosphoric acid, bis(2-ethylhexyl) ester, compd. with 2,2'-(cocoalkylimino) bis(ethanol), Phosphoric acid, mono(2-ethylhexyl) ester, compds. with diethanolamine N-coco alkyl derivs. (1:1)
OPP Chemical Codes:	111286, 129079, 129080
CAS Registry No.:	1070-03-7, 68649-38-7, 120579-32-0
Case Number:	4122
Empirical Formula:	H_3PO_4
Molecular Weight:	98.0
Highest Percentage of Active:	66.4%

Chemical Structure:



Chemical Properties:

Molecular Weight: 210.21 g/mol

Boiling Point: 354.51 °C

Melting Point: 81.3 °C

Vapor Pressure: 5.34 x 10^{-07} mm Hg @ 25 °C

Log $K_{ow:}$ 2.65

Log $K_{oc:}$ 2.112

Solubility in Water: 2192.2 mg/L

Henry's Law Constant: 6.99 x 10^{-10} atm m^3/mol

Half Life: 0.325 days

C. Use Profile

Information on the currently registered uses of organic esters of phosphoric acid-containing products and an overview of use sites and application methods follows. The detailed table of uses for organic esters of phosphoric acid products eligible for reregistration is contained in Appendix A.

Type of Pesticide: Disinfectant, fungicide, microbicide/microbistat

Use Sites:

Materials Preservatives
Carpet backing; floor and carpet shampoo; epoxy flooring and tile; vinyl products, including wall coverings, car tops, awnings, tarpaulins, tents, sails, drapes, shower curtains, cubicle curtains, and film (to be used for purposes other than food storage and flooring products); plastic furniture, excluding use for food service and food storage; polymeric laminates (excluding laminates used for food preparation surfaces); polymer concrete; synthetic and non-woven textile products, including wall coverings, car tops, awnings, tarpaulins, tents, sails, drapes, shower curtains and cubicle curtains; polymeric packaging film (to be used for purposes other than food storage); water, oil, solvent based paints, stains, other coating systems (for use on interior and exterior surfaces); substrates, machinery and equipment, including heating and ventilating and air conditioning systems; molded polymeric and polymer concrete bath tubs, showers, bathroom sinks, bathroom countertops and bathroom accessories; various molded polymer, and polymer concrete products for general household, industrial, commercial and health care use; natural and synthetic polymeric sealants, adhesives and caulking compounds; textile upholstery; mattresses, mattresses ticking and mattress covers; vinyl upholstery, air filters to be used in furnaces, air conditioners and air purification devices; automobiles and re-circulating air handling systems and human clothing

Target Pests: Mold/mildew, deterioration/spoilage bacteria, fungi, animal pathogenic bacteria

Formulation Types: soluble concentrate; polymer bead

Methods and Rates of Application:

The methods and rates of application for organic esters of phosphoric acid-containing products vary greatly depending on use site. The following methods and rates of application come from the representative exposure scenarios assessed in this document:

Paint: 0.1% - 5% a.i. by weight using a brush/roller or airless sprayer

Carpet cleaners: 0.1% - 5% a.i. by weight using a low pressure spray to simulate rug shampoo machine; during a meeting (11/7/07), the registrant indicated that the treated carpet cleaner is diluted prior to use by the consumer at a rate of 1 oz product/ 1 gallon of water

Vinyl floor: 5% a.i. by weight

Textiles (clothing/linen): 0.75% - 2% a.i. by weight of fabric

Mattresses: 1% - 2% a.i. by weight

Use Classification: General Use

Basic Manufacturer: Interface Research Corporation

III. Summary of Organic Esters of Phosphoric Acid Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for organic esters of phosphoric acid. While the risk assessments and related addenda are not included in this document, they are available from the U.S. Federal Government Public Docket at www.regulations.gov. The docket identification number is EPA-HQ-OPP-2007-1166. Hard copies of these documents may be found in the OPP public docket which is located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m.to 4:00 p.m.

The Agency's use of human studies in the organic esters of phosphoric acid risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

A. Human Health Risk Assessment

1. Toxicity of Organic Esters of Phosphoric Acid

A brief overview of the toxicity studies used for determining endpoints in the risk assessments are outlined below in Table 1. Further details on the toxicity of organic esters of phosphoric acid can be found in the *Organic Esters of Phosphoric Acid: Toxicology Disciplinary Chapter for the Issuance of the Reregistration Eligibility Decision (RED) Document*, dated 2/26/08; and *Organic Esters of Phosphoric Acid. Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document*, dated 3/4/08. These documents are available on the U.S. Federal Government Public Docket website at www.regulations.gov (Docket ID #EPA-HQ-OPP-2007-1166).

The Agency has reviewed all toxicity studies submitted to support guideline requirements for organic esters of phosphoric acid. Major features of the toxicology profile are presented in Table 1. Dermal sensitization studies are currently unavailable, but are needed for the reregistration of any organic esters of phosphoric acid uses, as well as an in vivo mammalian micronucleus test. Additional studies (see Chapter V., Table 19) are needed to assess exposure in the occupational and residential settings for the use of organic esters of phosphoric acid.

Table 1. Acute Toxicity Studies for Organic Esters of Phosphoric Acid			
Guideline No./ Study Type	**MRID No.**	**Results**	**Toxicity Category**
870.1100 Acute oral, rat (Purity not reported)	42907901	LD_{50} (M/F) > 5000 mg/kg (observed)	IV
870.1200 Acute dermal, rabbit (Purity not reported)	42907902	LD_{50} (M/F) > 5000 mg/kg (observed)	IV
870.1300 Acute inhalation, rat (Purity 60%)	40423801, supplements 41365401 & 41365402	LC_{50} (M/F) = 1.48 mg/L LC_{50} (M) = 1.43 mg/L LC_{50} (F) = 1.53 mg/L	III
870.2400 Primary eye irritation, rabbit (Purity not reported)	44858903	mildly irritating	III
870.2500 Primary dermal irritation, rabbit (Purity not reported)	44858904	Not irritating	IV
870.2600 Dermal sensitization	No study available		

The doses and toxicological endpoints selected by the Agency for the various exposure scenarios are summarized below in Table 2.

Table 2. Summary of Toxicological Doses and Endpoints for Organic Esters of Phosphoric Acid			
Exposure Scenario	**Dose Used in Risk Assessment (mg/kg/day)**	**Target MOE, UF, for Risk Assessment**	**Study and Toxicological Effects**
Dietary Risk Assessments			
Acute Dietary (all populations)	**This risk assessment is not currently required**		

Table 2. Summary of Toxicological Doses and Endpoints for Organic Esters of Phosphoric Acid			
Exposure Scenario	**Dose Used in Risk Assessment (mg/kg/day)**	**Target MOE, UF, for Risk Assessment**	**Study and Toxicological Effects**
Chronic Dietary (all populations)	**This risk assessment is not currently required**		
Non-Dietary Risk Assessments			
Incidental Oral Short-Term (1-30days) and Intermediate-Term (30 days-6 months)	**NOAEL (males)** = 62.5	**MOE** = 100 (10x inter-species extrapolation, 10x intra-species variation)	90-Day (Oral) Subchronic Toxicity Study in Rats (MRID 41083601) **LOAEL (males)** = 200 mg/kg/day based on decreased body weights and body weight gain and food consumption.
Dermal Short-Term (1-30days) and Intermediate-Term (30 days-6 months)	**NOAEL (males)** = 62.5	**MOE** = 100 (10x inter-species extrapolation, 10x intra-species variation)	90-Day (Oral) Subchronic Toxicity Study in Rats (MRID 41083601) **LOAEL (males)** = 200 mg/kg/day based on decreased body weights and body weight gain and food consumption.
Dermal Long-Term (> 6 months)	**NOAEL (males)** = 62.5	**MOE** = 300 (10x inter-species extrapolation, 10x intra-species variation, 3x for use of a subchronic endpoint for the long-term endpoint)	90-Day (Oral) Subchronic Toxicity Study in Rats (MRID 41083601) **LOAEL (males)** = 200 mg/kg/day based on decreased body weights and body weight gain and food consumption.
Inhalation Short-Term (1-30days) and Intermediate-Term (30 days-6 months)	**NOAEL (males)** = 62.5	**MOE** = 1000 (10x inter-species extrapolation, 10x intra-species variation, 10x route-to-route extrapolation) [a]	90-Day (Oral) Subchronic Toxicity Study in Rats (MRID 41083601) **LOAEL (males)** = 200 mg/kg/day based on decreased body weights and body weight gain and food consumption.
Cancer (oral, dermal, inhalation)	No carcinogenicity data available for Organic Esters of Phosphoric Acid.		

NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, MOE = margin of exposure, UF = uncertainty factor

[a] The inhalation absorption factor of 100% (default value, assuming oral and inhalation absorption are equivalent) should be used since an oral endpoint was selected for the inhalation exposure scenarios. If results are below an MOE of 1,000, a confirmatory inhalation study is warranted.

General Toxicity Observations

Acute Toxicity: The acute toxicity profile for organic esters of phosphoric acid is considered incomplete because no study is available for dermal sensitization. Except for the dermal sensitization study, all other acute studies were available for organic esters of phosphoric acid. However, many of the acute studies were not tested using the technical grade active ingredient. From the available acute toxicity data, it was found that organic esters of phosphoric acid are low in toxicity (Toxicity Category IV) for acute oral and dermal toxicity, with an observed lethal dose greater than 5000 mg/kg (MRIDs 42907901 and 42907902). The acute inhalation toxicity was examined in rats (MRIDs 40423801, purity 60%), and mortality was observed at all concentrations during the study (1.27, 2.32, 2.82, or 4.75 mg/L), resulting in an LD_{50} determination of 1.48 mg/L (combined) (Toxicity Category III). Organic esters of phosphoric acid were shown to be mildly irritating to the eyes (Toxicity Category III), and are not a dermal irritant (Toxicity Category IV).

Subchronic Toxicity: The only study available to assess subchronic toxicity is a 90-day oral toxicity study in the rat (MRID 41083601). Therefore, the database for subchronic toxicity is considered incomplete. The systemic LOAEL in males is 200 mg/kg/day based on decreased body weight, body weight gain, and food consumption and forestomach lesions (gastritis/ulcer-erosion/squamous hyperplasia hyperkeratosis); the NOAEL in males is 62.5 mg/kg/day. The LOAEL for females is 375 mg/kg/day based on decreased body weight, body weight gain, food consumption, and lenticular degeneration; the NOAEL in females is 120 mg/kg/day. In the absence of a route-specific toxicity study, a dermal absorption factor of 100% is used in conjunction with the endpoint selected from the 90-day oral toxicity study to assess dermal risks.

Prenatal Developmental Toxicity: The database for prenatal developmental toxicity is considered adequate for the currently registered uses. Developmental toxicity assessment for organic esters of phosphoric acid is based on a developmental study in the rat (MRID 41151601). The developmental toxicity LOAEL is 250 mg/kg/day based on dose-related increases in the number of litters with fetuses with skeletal and visceral abnormalities. The developmental toxicity NOAEL is 125 mg/kg/day.

Reproductive Toxicity: The assessment for reproductive toxicity is considered to be unnecessary for the current uses of this chemical. No reproductive toxicity studies are needed at this time.

Chronic Toxicity: The assessment for chronic toxicity is considered to be unnecessary for the currently registered uses of organic esters of phosphoric acid. No chronic toxicity studies are needed at this time.

Carcinogenicity: The assessment for carcinogenicity is considered to be unnecessary for the currently registered uses of organic esters of phosphoric acid. Negative findings were reported in the available genetic toxicity studies. No carcinogenicity studies are needed at this time.

Mutagenicity: The database for mutagenicity is considered incomplete. There are no *in vitro* mammalian cells gene mutation assay or *in vivo* mammalian micronucleus assay studies available. A few *in vitro* gene mutation assays are available to the Agency and are considered to be adequate in assessing *in vitro* gene mutation concerns. However, there are no data available to assess *in vivo* mutagenicity. Therefore, an *in vivo* mammalian micronucleus assay (870.5395) must be conducted to support the current uses of organic esters of phosphoric acid.

In a reverse gene mutation assay in bacteria (MRID 40564601) strains of *S. typhimurium* were exposed to Intercept in DMSO at concentrations of 0.005, 0.01, and 0/5 uL/plate in the presence and absence of mammalian metabolic activation (S9-mix). There was no evidence of induced mutant colonies over background levels in this study.

In a mammalian cell cytogenics assay (MRID 40564603) Chinese hamster ovary cell cultures were exposed to Intersept in DMSO. There was no statistically significant increase in the percentage of cells with aberrations, the number of aberrations per cell compared to the solvent controls. Therefore, no evidence of chromosomal aberrations induced over background levels was seen in this study.

Neurotoxicity: From the available repeated-dose toxicity studies, there was no evidence of neurotoxicity of organic esters of phosphoric acid. It is concluded that there is no concern for neurotoxicity resulting from exposure to organic esters of phosphoric acid for its currently registered uses. Therefore, these studies are not needed at this time.

Metabolism and Pharmacokinetics: No pharmacokinetics and metabolism studies are available for organic esters of phosphoric acid. These studies are not needed at this time.

Endocrine Disruption Potential. EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals,

EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disrupting Screening Program (EDSP) have been developed, organic esters of phosphoric acid may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

2. FQPA Safety Factor

The Agency has determined that analysis of the potential need for a special hazard-based safety factor under the FQPA is not needed at this time. The Agency does not anticipate dietary or drinking water exposures based on the registered use patterns and there are no tolerances or tolerance exemptions for the use of organic esters of phosphoric acid as an active ingredient. Therefore, an FQPA hazard analysis is not necessary at this time.

3. Dietary and Drinking Water Risk Summary

Based on the use patterns of organic esters of phosphoric acid, it is not expected that there will be any dietary exposure. Therefore, it was not necessary to conduct a dietary assessment. Furthermore, since these uses occur in an indoor environment, it is not expected that organic esters of phosphoric acid will impact any source of drinking water. Therefore, a drinking water assessment was not conducted.

4. Residential Risk Assessment

The residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food or in drinking water. Although no products containing organic esters of phosphoric acid are labeled for residential use, residents may be exposed to household items that have been treated with organic esters of phosphoric acid through material preservation (e.g., paints, textiles, mattresses, carpet/floor cleaners). Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as an MOE (Margin of Exposure) which is the ratio of estimated exposure to an appropriate NOAEL (No Observed Adverse Effect Level). The types of products treated with organic esters of phosphoric acid that are handled in a residential setting are treated paints, textiles, mattresses, vinyl products, carpet and floor cleaners, and similar products as described in Table 3. The short-term inhalation and dermal residential painter and carpet cleaner exposures were assessed and are considered to be representative of all other residential handler exposures. Only short-term exposure durations (1 to 30 days) were estimated because it was assumed that a homeowner or do-it-yourself painter and carpet cleaning would typically occur on an intermittent basis. Post-application scenarios have been developed that encompass high-end exposure scenarios that are representative of all uses. Representative post-application scenarios assessed include contacting carpets cleaned with treated shampoo (dermal and incidental oral exposure of children), contacting treated vinyl floors (dermal and incidental oral

exposure of children), wearing treated clothing (dermal exposure of children and adults), mouthing treated textiles such as clothing and blankets (incidental oral exposure to children), and contacting treated mattresses/covers (dermal exposure to children and adults). Because organic esters of phosphoric acid have a relatively low vapor pressure, post-application inhalation exposures were not assessed. Additional information can be found in the "Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic Esters of Phosphoric Acid for the Reregistration Eligibility Decision Document," dated December 1, 2007; and the "Organic Esters of Phosphoric Acid Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision Document," dated March 4, 2008.

Table 3. Representative Uses Associated with Residential Exposure

Representative Use	Exposure Scenario	Application Method	Registration #	Application Rate
Using treated paints	ST handler: dermal and inhalation	• brush/ roller • airless sprayer	43670-1	0.1% - 5% a.i. by weight
Using treated carpet cleaners	ST handler: dermal and inhalation	Low pressure spray to simulate rug shampoo machine	43670-1	0.0033 lb a.i./gal and 6.5e-5 lb a.i./gal (5% a.i. x 8.34 lb/gal x 1 oz product/gal water x 1 gal/128 oz = 0.0033 lb a.i./gal)[a]
	ST and IT post-app: child incidental ingestion and dermal	N/A		0.1% - 5% a.i. by weight
Treated vinyl floor	ST and IT post-app: child incidental ingestion and dermal	N/A	43670-1	5% a.i. by weight
Using treated textiles (e.g., clothing and linen)	ST post-app: child incidental ingestion and dermal	N/A	43670-1	0.75% - 2% a.i. by weight [b]
Using treated mattresses	ST and IT post-app: child dermal	N/A	43670-1	1% - 2% a.i. by weight

a: Note that during a meeting on 11/7/07, the registrant indicated that the treated carpet cleaner is diluted prior to use by the consumer at a rate of 1 oz product/ 1 gallon of water

b: Note that during a meeting on 11/7/07, the registrant indicated that the topical textile treatment rate is 0.75% - 2%ai by weight of fabric.

a. Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary risks for organic esters of phosphoric are listed in Table 2.

An MOE greater than or equal to 100 is considered adequately protective for the residential dermal exposure assessment and for the incidental oral exposure to children. The MOE of 100 includes 10x for interspecies extrapolation and 10x for intraspecies variation. An MOE greater than or equal to 1000 was selected for the inhalation routes of exposure. A target MOE of 1000 includes an uncertainty factor (UF) of 10x for inter-species extrapolation, 10x for intraspecies variation, and an additional 10x has been added for route-to-route extrapolation as there is no inhalation study available. For organic esters of phosphoric acid, an inhalation MOE greater than or equal to 100 is considered adequately protective for inhalation exposures. However, if the inhalation MOE is less than 1,000, confirmatory inhalation toxicity data may be needed to confirm that the use of route-to-route extrapolation does not underestimate risk.

b. Residential Handler

i. Exposure Scenarios, Data and Assumptions

Although no products containing organic esters of phosphoric acid are labeled for residential use, residents may be exposed to household items that have been treated with organic esters of phosphoric acid through material preservation (e.g., paints, textiles, mattresses, carpet and floor cleaners, etc.). Risks to residential handlers are assessed differently than occupational handlers in that homeowners are assumed to complete all elements of an application without the use of personal protective equipment.

The types of products treated with organic esters of phosphoric acid that are handled in a residential setting are treated paints, textiles, mattresses, vinyl products, carpet and floor cleaners, and similar products as described in Table 4.1 of the *Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic Acid Esters of Phosphoric Acid for the Reregistration Eligibility Decision (RED) Document,* dated 12/1/07. The short-term inhalation and dermal residential painter and carpet cleaner exposures were assessed and are considered to be representative of all other residential handler exposures. Maximum application rates, related use information and Agency standard values were used to assess residential handler exposure. Only short-term exposure durations (1 to 30 days) were estimated because it was assumed that use by a homeowner or do-it-yourself painter and carpet cleaners would typically occur on an intermittent basis. In addition, homeowners are assumed to use different products with varying activities, not exclusively organic esters of phosphoric-treated products.

There are no chemical-specific exposure data to assess residential handler exposures, however, surrogate data are available for painting with a brush and an airless sprayer and applying carpet cleaners using a low pressure handwand. The surrogate data

are based on PHED (Pesticide Handler Exposure Database) data for painters and CMA (Chemical Manufacturers Association) data for carpet cleaners wearing no gloves or respiratory protection.

For the *brush/roller* scenario, the PHED dermal and inhalation unit exposure values for a residential handler applying a pesticide using a paint brush were used. The test subjects were painting a bathroom with a paint brush. The dermal unit exposure value (230 mg/lb a.i.) represents a handler wearing short pants, short sleeves and no gloves. The inhalation unit exposure value (0.28 mg/lb a.i.) represents a handler wearing no respiratory protection.

For the *airless sprayer* scenario, the PHED unit exposure values for a residential handler applying a pesticide using an airless sprayer were used. The test subjects were staining the outside of a house with an airless sprayer. Although these exposures may differ slightly from exposures of painters to organic esters of phosphoric-preserved products, these data are judged to be adequately representative. The dermal unit exposure value (79 mg/lb a.i.) represents a handler wearing short pants, short sleeves and no gloves. The inhalation unit exposure value (0.83 mg/lb a.i.) represents a handler wearing no respiratory protection.

For the *low pressure hand wand* scenario, the CMA unit exposure value for a low pressure spray was used for the residential carpet cleaner. The dermal unit exposure value (191 mg/lb a.i.) represents a handler wearing no gloves. The inhalation unit exposure value (0.681 mg/lb ai) represents a handler wearing no respiratory protection. The values were based on data collected from eight individuals who hand sprayed carpet using 200 psi, and then used a push broom rake to raise the carpet nap.

The quantities handled/treated were estimated based on standard Agency assumptions:

- For the ***brush/roller*** method in ***paint applications***, it is assumed that 20 lbs (approximately 2 gallons) of treated paint will be used. This is based on the 90th percentile value of 8 gallons of latex paint used per year divided by the mean frequency of 4 painting events/year.
- For the ***airless sprayer*** method in ***paint applications***, it is assumed that 150 lbs (approximately 15 gallons) of treated paint will be used. This is based on the coverage of 200 ft^2/gallon and a house size of 40 x 30 x 20 ft (surface area of 2,800 ft^2).
- For the ***low pressure hand wand*** method for ***carpet shampoo applications***, it was assumed that 2 gallons are used in all indoor applications.

ii. Risk Estimates

Based on toxicological criteria and potential for exposure, the Agency conducted dermal and inhalation exposure assessments. As noted previously, MOEs greater than or equal to 100 for both the dermal and inhalation routes of are considered adequately

protective for the residential exposure assessment. For inhalation exposure, the target MOE for identifying risks of concern is 100 and the target MOE for identifying the need for inhalation toxicity data is 1000. An inhalation MOE greater than or equal to 100 is considered adequately protective. However if the inhalation MOE is greater then 100 but less then 1,000, inhalation toxicity data may be needed to confirm that the use of route-to-route extrapolation does not underestimate inhalation exposure risk. For the organic esters of phosphoric acid, the inhalation endpoint was set using oral toxicity data.

Table 4 presents the calculations of the dermal and inhalation doses and MOEs for a residential painter working with treated paint and residential carpet cleaners. The short-term dermal and inhalation MOEs estimated for painters at the lower application rate and carpet cleaners at the maximum rate are above the target MOE of 100 and not a concern. However, the short-term dermal MOEs estimated for painters at the maximum application rate are below the target MOE of 100 and therefore a concern. In addition, the short-term inhalation MOE estimated for painters at the maximum application rate using the airless sprayer method is 700. Although this MOE is above 100, it is below 1000 which indicates that an inhalation specific toxicity study may be warranted to confirm that the use of route-to-route extrapolation does not underestimate inhalation exposure risk for this exposure scenario. The target MOE for identifying inhalation risks of concern is 100 and the target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000 (10x for inter-species extrapolation; 10x for intraspecies variation; and 10x for route-to-route extrapolation). An inhalation absorption factor of 100% was used (equivalency to oral absorption was assumed) for all inhalation exposure durations since the MOE calculations are based on an oral endpoint. Since the short-term airless sprayer inhalation MOE is below 1,000 for organic esters of phosphoric acid, confirmatory inhalation data may be needed.

Table 4. Short-Term Residential Handler Exposures and MOEs										
Exposure Scenario	**Application Method**	**Application Rate[a]**	**Quantity Handled per day[b]**	**Dermal Unit Exposure (mg/lb a.i.)**	**Inhalation Unit Exposure (mg/lb a.i.)**	**Dermal Daily Dose (mg/kg/day) [c]**	**Inhalation Daily Dose (mg/kg/day) [c]**	**Dermal MOE [d] (Target MOE = 100)**	**Inhalation MOE [d] (Target MOE = 100)**	**Total MOE**
Carpet cleaners	Low Pressure Spray	6.5E-5 lb a.i./gal	2 gal	191	0.681	1.8E-04	6.3E-07	350,000	99,000,000	350,000
		0.0033lb ai/gal	2 gal	191	0.681	8.9E-03	3.2E-05	7,000	2,000,000	7,000
Painting	Paint brush	0.1% a.i. by wt	20 lbs	230	0.28	0.066	8.0E-05	950	780,000	950
		5% a.i. by wt	20 lbs	230	0.28	3.3	0.0040	**19**	16,000	**19**
	Airless sprayer	0.1% a.i. by wt	150 lbs	79	0.83	0.17	0.0018	370	35,000	370
		5% a.i. by wt	150 lbs	79	0.83	8.46	0.089	**7**	**700**	**7**

a Application rates are based on the minimum and maximum application rates determined from EPA registered labels (see Table 4.1).

b Amount handled per day values are standard EPA assumptions

c Daily dose (mg/kg/day) = [unit exposure (mg/lb a.i.) x application rate (% a.i. weight or lb a.i./gal) x quantity handled (lb/day or gal/day) x absorption factor (1.0 for dermal and inhalation)]/ Body weight (70 kg).

d MOE = NOAEL / Daily Dose. [Where short-term dermal and inhalation NOAEL = 62.5 mg/kg/day]. Target MOE = 1000.

e Total MOE = 1/((1/MOEdermal) + (1/MOEinhal))

c. Residential Post-Application

i. Exposure Scenarios, Data and Assumptions

Residential post-application exposures occur when adults and children contact areas in which an antimicrobial end use product has recently been applied or when children incidentally ingest the pesticide residues through mouthing treated products/treated articles (i.e., hand-to-mouth or object-to-mouth contact). For the purposes of this screening level assessment, post-application scenarios have been developed that encompass high end exposure scenarios that are representative of all uses. Table 3 shows representative post-application scenarios assessed which include: contacting carpets cleaned with treated shampoo (dermal and incidental oral exposure of children), contacting treated vinyl floors (dermal and incidental oral exposure of children), wearing treated clothing (dermal exposure of children and adults), mouthing treated textiles such as clothing and blankets (incidental oral exposure to children), and contacting treated mattresses/covers (dermal exposure to children and adults). One of the primary uses of organic esters of phosphoric acid is for preservation of carpet backing. Exposure to carpet backing is considered to be negligible and therefore was not quantitatively assessed. In addition, because the organic esters of phosphoric acid have a relatively low vapor pressure, post-application inhalation exposures were not assessed.

Typically, post-application exposures in residential settings are assumed to occur over a short-term duration (1 to 30 days) as episodic, not daily events. It is believed that the use of carpet shampoo may result in intermediate-term (IT) residential exposure to children contacting treated carpet. Therefore, IT post-application exposures were assessed for the organic esters of phosphoric acid. In addition, toddlers (3 years old) were used to represent the 1 to 6 year old age group. A body surface area of 0.657 m^2 and a body weight of 15 kg were assumed, which are the median values for 3 year olds (USEPA, 1997).

ii. Risk Estimates

Carpet Shampoo

Flooring maintenance products such as carpet shampoos can be treated/preserved with organic esters of phosphoric acid during the manufacturing process. Therefore, post- application dermal and incidental oral exposures to treated carpet may occur. Since the carpet in facilities such as daycares can be cleaned on a regular basis, there is potential for exposure to occur everyday, assuming that organic esters of phosphoric acid have a relatively long half life in indoor environments. The potentially longer half life supports both a short- and intermediate-term exposure assessment.

For the dermal and incidental oral scenarios that include contact with carpet cleaned with treated shampoo, the Agency has no data regarding the quantity of solution residue left on the carpet after treatment. As a conservative measure, it has been assumed that 25% of the cleaning solution remains after the final cleaning (standard Agency assumption). No transferable residue data were available that could be used to estimate the transfer of the active ingredient from the carpet to the skin of children. Therefore, it is assumed that 100% and 5% of the residue on the treated carpet is available for dermal transfer (USEPA, 2000 and 2001). Confirmatory dermal transfer data is needed to support the 5% transfer rate. It should be noted that the registrant indicated that they will submit leaching/extraction data. As soon as these data are submitted and reviewed, the results will be incorporated into the assessment, as appropriate.

Children's Dermal Exposure from Treated Carpet Shampoo

There is the potential for short and intermediate-term dermal exposures when children come into contact with carpeting cleaned with treated shampoo. Exposures and MOEs were evaluated for children contacting treated carpet in residential homes. See the *Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic Acid Esters of Phosphoric Acid for the Reregistration Eligibility Decision (RED) Document,* dated 12/1/07 for a detailed explanation of the assumptions used in the calculations.

Table 5 shows the calculations of the short- and intermediate-term dermal doses and MOEs for children contacting carpet cleaned with treated shampoo. All of the MOEs are above the target MOE of 100 and therefore not a concern.

Table 5. Short-term and Intermediate-term Dermal Post-Application Exposures and MOEs for Toddlers Contacting Carpets Cleaned with Treated Shampoo							
Treatment solution (lb a.i./gallon)	**Treatment coverage (gal/ft^2)**	**Fraction remaining after cleaning (%)**	**Carpet conc. ($mg\ ai/m^2$)**	**Transferable residue from carpet to skin (%)**	**Surface area of skin in contact with carpet (m^2/day)**	**Dermal daily dose[b] (mg/kg/ day)**	**Dermal MOE[c] (Target MOE=100)**
6.5e-5	300	25%	0.27	100%	0.657	0.012	5400
6.5e-5	300	25%	0.27	5%	0.657	0.00058	110,000
0.0033	300	25%	13.3	100%	0.657	0.58	110
0.0033	300	25%	13.3	5%	0.657	0.029	2,100

a. Carpet conc. (mg/m^2) = (trt. sol. lb a.i./gal) x (1 gal/300 ft^2 carpet) x (10.8 ft^2/m^2) x (454 gram/lb) x (1000 mg/gram)

b. Dermal Daily Dose (mg/kg/day) = carpet conc (mg/m^2) x surface area of skin in contact with carpet (m^2/day) x transferable residue from carpet to skin (%) x dermal absorption (100%) / body weight (kg)

c. Dermal MOE = NOAEL (62.5 mg/kg/day) / Dermal Daily Dose (mg/kg/day)

Children's Incidental Ingestion Exposure from Treated Carpet Shampoo

There is potential for short- and intermediate-term incidental oral exposures when children exhibit hand-to-mouth behavior and contact carpet cleaned with organic esters of phosphoric acid-treated shampoo. Incidental oral exposures and MOEs were estimated for children contacting treated carpet in residential or commercial day care settings. See the *Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic Acid Esters of Phosphoric Acid for the Reregistration Eligibility Decision (RED) Document,* dated 12/1/07 for a detailed explanation of the assumptions used in the calculations.

Table 6 shows the calculations of the short- and intermediate-term incidental oral exposures and resulting MOEs for children contacting carpet cleaned with treated shampoo. The MOEs in all scenarios except for two are above the target MOE of 100. The short-term oral MOE at the highest application rate with an assumed 100% residue transfer to skin is below the target MOE of 100 (MOE = 44) and the intermediate-term oral MOE at the highest application and 100% assumed residue transfer to skin is below the target MOE of 100 (MOE = 93). Due to the conservative nature of this assessment, the Agency does not have a concern for the incidental oral MOE of 93 for children coming into carpet cleaned with organic esters of phosphoric acid-treated shampoo.

Table 6. Short-term and Intermediate-term Oral Post-Application Exposures and MOEs for Toddlers Contacting Carpets Cleaned with Treated Shampoo										
Treatment solution (lb a.i./gallon)	**Treatment coverage (gal/ft^2)**	**Fraction remaining after cleaning (%)**	**Carpet conc.[a] (mg ai/cm^2)**	**Transferable residue from carpet to skin (%)**	**Surface area of hand in contact with carpet and mouth (cm^2/event)**	**Frequency of hand to mouth (event/hr)**	**Exposure Time (hr/day)**	**Saliva Extraction (%)**	**Oral daily dose[b] (mg/kg/day)**	**Oral MOE[c] (Target MOE=100)**
Short –Term										
6.5e-5	300	25%	0.00027	100%	20	20	8	50	0.028	2,200
6.5e-5	300	25%	0.00027	5%	20	20	8	50	0.0014	44,000
0.0033	300	25%	0.013	100%	20	20	8	50	1.4	**44**
0.0033	300	25%	0.013	5%	20	20	8	50	0.071	880
Intermediate-Term										
6.5e-5	300	25%	0.00027	100%	20	9.5	8	50	0.013	4,600
6.5e-5	300	25%	0.00027	5%	20	9.5	8	50	0.00067	93,000
0.0033	300	25%	0.013	100%	20	9.5	8	50	0.67	**93**
0.0033	300	25%	0.013	5%	20	9.5	8	50	0.034	1,900

a. Carpet conc. (mg/cm^2) = (trt. sol. lb a.i./gal) x (1 gal/300 ft^2 carpet) x (10.8 ft^2/m^2) x (454 gram/lb) x (1000 mg/gram) x (1000 cm^2/m^2)

b. Oral Daily Dose (mg/kg/day) = carpet conc (mg/m^2) x transferable residue from carpet to skin (%) x surface area hands (cm^2/day) x frequency (event/hr) x exposure time (hr/day) x saliva extraction (%)/ body weight (kg)

c. Oral MOE = NOAEL (62.5 mg/kg/day) / Oral Daily Dose (mg/kg/day)

Because the dermal and incidental oral toxicity endpoints are based on the same study, the Agency assessed Total MOEs. The Total MOEs for exposure to carpet cleaners are presented in Table 7. All Total MOEs except for those evaluated at the maximum application rate and 100% residue transfer are above the Target MOE of 100. However, a confirmatory residue dermal transfer study is needed to support the 5% transfer assumption.

Table 7. Short-term and Intermediate-term Total MOEs for Toddlers Contacting Carpets Cleaned with Treated Shampoo								
	Short-term MOEs				**Intermediate-term MOEs**			
	Min rate, 100% transfer	Min rate, 5% transfer	Max rate, 100% transfer	Max rate, 5% transfer	Min rate, 100% transfer	Min rate, 5% transfer	Max rate, 100% transfer	Max rate, 5% transfer
Dermal	5,400	110,00	110	2,100	5,400	110,00	110	2,100
Oral	2,200	44,000	44	880	4,600	93,000	93	1,900
Total	1,600	31,00	**31**	620	2,500	50,000	**50**	990

Total MOE = 1/ (1/MOEdermal) + (1/ MOE oral))

Treated Vinyl

Vinyl tiles used for flooring can be treated with organic esters of phosphoric acid during the manufacturing process. Therefore post-application dermal and incidental oral exposures to treated vinyl flooring may occur. Since the vinyl is impregnated with organic esters of phosphoric acid and the vinyl can be used in a residential setting, there is potential for exposure to occur everyday. In addition, the Agency assumed that organic esters of phosphoric acid have a relatively long half life in indoor environments. The potentially longer half life supports evaluation of both short- and intermediate-term exposure durations.

Children's Dermal Exposure from Treated Vinyl

There is the potential for short- and intermediate-term exposures to organic esters of phosphoric acid when children come into contact with treated vinyl flooring. Exposures and resulting MOEs were estimated for children contacting treated vinyl in residential homes. See the *Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic Acid Esters of Phosphoric Acid for the Reregistration Eligibility Decision (RED),* dated 12/1/07 document for a detailed explanation of the assumptions used in the calculations.

Table 8 shows the short- and intermediate-term dermal doses and resulting MOEs for children contacting treated vinyl. The short- and intermediate-term MOEs are above the target MOE of 100 and therefore not a concern.

Table 8. Short- and Intermediate-term Dermal Exposures and MOEs for Children Contacting Treated Vinyl Flooring

% a.i.	Vinyl density (g/cm^3)	Vinyl flooring thickness (mm)	Fraction available on surface of vinyl	Fraction transferred to skin	Skin surface area contacting vinyl (cm^2)	Dermal Exposure [a] (mg/kg/day)	ST/IT Dermal MOE (Target MOE= 100) [b]
5%	1.3	3	0.5%	10%	6570	0.043	1,500

a Equations used to estimate exposure are presented above.
b MOE = NOAEL/exposure [Where ST and IT NOAEL= 62.5 mg/kg/day].

Children's Incidental Ingestion Exposure from Treated Vinyl

There is potential for short- and intermediate-term incidental oral exposure when children exhibit hand-to-mouth behavior and contact vinyl flooring treated with organic esters of phosphoric acid. Incidental oral exposures and MOEs were calculated for children contacting treated vinyl in residential or commercial day care settings. See the *Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic*

Acid Esters of Phosphoric Acid for the Reregistration Eligibility Decision (RED) Document, dated 12/1/07 for a detailed explanation of the assumptions used in the calculations.

Table 9 shows the evaluation of the short- and intermediate-term incidental oral exposures and MOEs for children contacting treated vinyl. Both short- and intermediate-term MOEs are above the target MOE of 100 and therefore not a concern.

Table 9. Short- and Intermediate-term Incidental Oral Exposures and MOEs for Children Contacting Treated Vinyl Flooring

Duration	% a.i.	Vinyl density (g/cm^3)	Vinyl flooring thickness (mm)	Fraction available on surface of vinyl	Fraction transferred to skin	Saliva extraction efficiency	Surface area of hands (cm^2)	Frequency of hand-to-mouth events (events/hr)	Exposure time (hrs/day)	Exposure [a] (mg/kg/day)	ST/IT MOE (Target MOE = 100) [b]
Short-term	5%	1.3	3	0.5%	10%	50%	20	20	4	0.0052	12,000
Intermediate-term	5%	1.3	3	0.5%	10%	50%	20	9.5	4	0.0025	25,000

a Equations used to estimate exposure are presented above.
b MOE = NOAEL/exposure estimate [Where: ST and IT Oral NOAEL = 62.5 mg/kg/day].

Because the dermal and incidental oral toxicity endpoints are based on the same study, the Agency assessed total MOEs. The Total MOEs for exposure to treated vinyl are presented in Table 10. All Total MOEs are above the Target MOE of 100 and therefore not a concern.

Table 10. Short-term and Intermediate-term Total MOEs for Toddlers Contacting Treated Vinyl

	Short-term MOEs	Intermediate-term MOEs
	Max rate, 10% transfer	**Max rate, 10% transfer**
Dermal	1,500	1,500
Oral	12,000	25,000
Total	1,300	14,000

Total MOE = 1/ (1/MOEdermal) + (1/ MOE oral))

Textiles (Clothing)

Textiles (which include fabric used for clothes – outerwear and underwear) can be treated with organic esters of phosphoric acid after the manufacturing process via a topical treatment. Therefore post-application dermal and incidental oral exposures to treated clothing may occur. It was assumed that not all clothing is treated with organic esters of phosphoric acid and the clothing that is treated will not be worn everyday. Therefore exposure would occur intermittently. Thus only short-term exposure durations were assessed.

Dermal Exposure to Treated Clothing

There is potential for short-term dermal exposure when adults or children contact clothing made of textiles that have been commercially/industrially treated with organic esters of phosphoric acid. See the *Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic Acid Esters of Phosphoric Acid for the Reregistration Eligibility Decision (RED) Document,* dated 12/1/07 for a detailed explanation of the assumptions used in the calculations.

Table 11 shows the evaluation of the short-term dermal exposures and MOEs for children and adults contacting treated textile/clothing. All MOEs are below the target MOE of 100 and are therefore considered a concern.

Table 11. Short-term Dermal Exposure and MOE for Adults and Children Contacting Treated Clothing

Duration	% a.i.	Cloth density (mg/cm^2)	Fraction transferred to skin	Body Surface Area Contacting Cloth (cm^2/day)	Exposure [a] (mg/kg/day)	ST MOE (Target MOE = 100) [b]
Child						
ST	2%	10	100%	5670	75.6	**<1**
ST	2%	10	5%	5670	3.8	**17**
ST	0.75%	10	100%	5670	28.4	**2**
ST	0.75%	10	5%	5670	1.4	**44**
Adult						
ST	2%	10	100%	17,000	48.6	**1**
ST	2%	10	5%	17,000	2.4	**26**
ST	0.75%	10	100%	17,000	18.2	**3**
ST	0.75%	10	5%	17,000	0.9	**69**

a The equation used to estimate exposure is presented above.
b MOE = NOAEL/exposure [Where: ST dermal NOAEL = 62.5 mg/kg/day].

Children's Incidental Ingestion Exposure from Wearing Treated Clothing

The Agency assumed that not all clothing is treated with organic esters of phosphoric acid and the clothing that is treated will not be worn everyday and exposure would occur intermittently. Therefore there is potential for short-term incidental ingestion exposures when children come into contact with textiles treated with organic esters of phosphoric acid through mouthing behaviors. The incidental oral exposure to

organic esters of phosphoric acid was evaluated and MOEs were calculated for children contacting treated textiles. See the *Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic Acid Esters of Phosphoric Acid for the Reregistration Eligibility Decision (RED) Document,* dated 12/1/07 for a detailed explanation of the assumptions used in the calculations.

Table 12 shows the assessment of the short-term incidental oral exposures and MOEs for children mouthing treated textiles. Based on the application rate, the resulting MOEs range from 93 (highest application rate) to 250 (lowest application rate). However, due to the conservative nature of the assessment, the Agency does not have a risk concern for application of organic esters of phosphoric acid at the highest application rate in this scenario.

Table 12. Short-term Incidental Oral Exposures and MOEs for Children Contacting Treated Clothing

Duration	% a.i.	Cloth density (mg/cm^2)	Area of fabric mouthed (cm^2)	Saliva extraction efficiency	Exposure [a] (mg/kg/day)	ST MOE (Target MOE = 100) [b]
ST	2%	10	100	50%	0.67	**93**
ST	0.75 %	10	100	50%	0.25	250

a The equation used to estimate exposure is presented above.
b MOE = NOAEL/exposure [Where: ST oral NOAEL = 62.5 mg/kg/day].

Because the dermal and incidental oral toxicity endpoints are based on the same study, the Agency assessed Total MOEs. Since all of the dermal MOEs were below the target MOE the resulting Total MOEs will also be below the target MOE and are therefore a concern.

Mattresses

Textile and vinyl upholstery such as mattresses, mattress ticking and mattress covers can be treated with organic esters of phosphoric acid during the manufacturing process. Therefore post-application dermal exposures to treated mattresses may occur. It was assumed that exposure to a textile mattress cover will represent exposure to all other mattress components. Since the mattress cover is impregnated with organic esters of phosphoric acid and it can be used everyday, both short- and intermediate-term exposures durations were assessed.

Dermal Exposure to Treated Mattress Covers

There is the potential for short- and intermediate-term exposures when adults and children come into contact with mattress covers treated with organic esters of phosphoric

acid, through the regular use of the mattress. Exposures were evaluated and MOEs were calculated for children and adults contacting treated mattresses in residential homes. See the *Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic Acid Esters of Phosphoric Acid for the Reregistration Eligibility Decision (RED) Document,* dated 12/1/07 for a detailed explanation of the assumptions used in the calculations.

Table 13 presents the calculation of the short- and intermediate-term dermal exposures and resulting MOEs for children and adults contacting treated mattress covers. All scenarios represent a concern except for adults and children contacting the mattress cover treated at the lowest application rate (1%) and assuming 5% transfer to skin.

Table 13. Short- and Intermediate-term Dermal Exposures and MOEs for Children and Adults Contacting Treated Mattress Covers

Duration	% a.i.	Mattress density (mg/cm^2)	Fraction transferred to skin	Skin surface area contacting mattress (cm^2/day)	Protective factor (%)	Dermal Absorption (%)	ST and IT Exposure [a] (mg/kg/day)	MOE (Target MOE = 100) [b]
Children								
ST/IT	5%	10	100%	3,283	50%	100%	54.7	**1**
ST/IT	5%	10	5%	3,283	50%	100%	2.7	**23**
ST/IT	1%	10	100%	3,283	50%	100%	10.9	**6**
ST/IT	1%	10	5%	3,283	50%	100%	0.5	114
Adults								
ST/IT	5%	10	100%	9,220	50%	100%	32.9	**2**
ST/IT	5%	10	5%	9,220	50%	100%	1.6	**38**
ST/IT	1%	10	100%	9,220	50%	100%	6.6	**9**
ST/IT	1%	10	5%	9,220	50%	100%	0.3	190

a Equations used to estimate exposure are presented above.
b MOE = NOAEL/exposure [Where: ST and IT dermal NOAEL = 62.5 mg/kg/day].

5. Aggregate Risk

Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. Aggregate exposure is the total exposure to a single chemical (or its residues) that may occur from dietary (i.e., food and drinking water), residential, and other non-occupational sources, and from plausible exposure routes (oral, dermal, and inhalation). Based on the currently registered use patterns of organic esters of phosphoric acid, the Agency did not

conduct a dietary exposure assessment as there are no food uses. However, this assessment includes non-dietary residential aggregate exposures and risks.

In performing aggregate exposure and risk assessments, the Office of Pesticide Programs has published guidance outlining the necessary steps to perform such assessments (General Principles for Performing Aggregate Exposure and Risk Assessments, November 28, 2001; available at: http://www.epa.gov/pesticides/trac/science/aggregate.pdf . Steps for deciding whether to perform aggregate exposure and risk assessments are listed and include: identification of toxicological endpoints for each exposure route and duration; identification of potential exposures for each pathway (food, water, and/or residential); reconciliation of durations and pathways of exposure with durations and pathways of health effects; determination of which possible residential exposure scenarios are likely to occur together within a given time frame; determination of magnitude and duration of exposure for all exposure combinations; determination of the appropriate technique (deterministic or probabilistic) for exposure assessment; and determination of the appropriate risk metric to estimate aggregate risk.

Typically, aggregate risk assessments are conducted for acute (1 day), short-term (1-30 days), intermediate-term (1-6 months) and chronic (6 months to lifetime) exposures. However, an acute aggregate assessment was not conducted because there are no adverse effects attributable to acute exposure. In addition, because there are no long-term residential exposures, the chronic aggregate assessment was not conducted. Thus, only short-and intermediate-term aggregate assessments were conducted. Oral and dermal exposure and risk estimates were combined for the aggregate risk. Since the endpoint for each route of exposure was based on the same oral study resulting in the same effects, all of the routes of exposure were included in the aggregate assessment. Table 14 presents the short- and intermediate-term aggregate assessment.

Table 14. Summary of Exposure Scenarios Included in the Short- and Intermediate-Term Aggregate Assessments

	Short-term Aggregate
Adults	Dermal: • exposure to residues during **carpet** cleaning • exposure to residues in **mattresses** preserved during manufacturing Inhalation: • exposure to residues during **carpet** cleaning
Children	Dermal: • exposure to residues in **carpet cleaner** residues preserved during manufacturing • exposure to residues in **mattresses** preserved during manufacturing • exposure to residues in **vinyl tiles** preserved during manufacturing Oral: • exposure to residues in **carpet cleaner** residues preserved during manufacturing • exposure to residues in **vinyl tiles** preserved during manufacturing

Table 14. Summary of Exposure Scenarios Included in the Short- and Intermediate-Term Aggregate Assessments	
	Intermediate-Term Aggregate
Children	Dermal: • exposure to residues in **carpet cleaner** residues • exposure to residues in **mattresses** preserved during manufacturing • exposure to residues in **vinyl tiles** preserved during manufacturing • Oral: • exposure to residues in **vinyl tiles** preserved during manufacturing • exposure to residues in **carpet cleaner** residues

a. Short- and Intermediate-Term Aggregate Risk

This assessment considers the short- and intermediate-term aggregate exposures and risks for adults and children who could be exposed to organic esters of phosphoric acid residues from the use of products in non-occupational environments.

The post-application exposures to textile/clothing organic esters of phosphoric acid residues alone are of concern to the Agency. Incorporation of this scenario in the aggregate assessment would result in risks of concern. Therefore, the textile scenario was not incorporated in the aggregate assessment. If these exposures had not resulted in risks of concern, then they would have been included in the aggregate assessments. For the mattress scenario, the MOE used in the aggregate assessment was based on the minimum application rate because the MOE at the maximum application rate was below the Agency's Target MOE of 100 and cannot be aggregated.

i. Short-term Aggregate Assessment

For children, the short-term aggregate assessment includes dermal exposures to shampoo residues in carpets, mattresses and vinyl tiles and incidental oral exposure to shampoo residues in carpets and vinyl tiles.

For adults, the short-term aggregate assessment includes dermal exposure to residues during carpet cleaning, mattress covers treated with organic esters of phosphoric acid and inhalation exposure to residues during carpet cleaning.

The short- term aggregate MOE for children is 86, and therefore of concern as it is below the target MOE of 100. The adult short-term aggregate assessment was above the target MOE of 100 (MOE = 185) and therefore not of concern. Table 15 presents a summary of the children's short-term aggregate risk MOE.

Table 15. Summary of Child Short-Term Aggregate Risk Estimates	
Exposure Scenario	**Total MOE[b] (Target MOE≥100)**

Table 15. Summary of Child Short-Term Aggregate Risk Estimates	
Exposure Scenario	**Total MOE[b] (Target MOE≥100)**
Dermal Exposure	
Mattress	110
Vinyl	1,500
Carpet Shampoo	2,100
Oral Exposure	
Vinyl	12,000
Carpet Shampoo	620
Total Aggregate Dose and MOE	**86**

a: Aggregate MOE = 1/((1/MOE mattress dermal) + (1/MOE vinyl dermal) + (1/MOE vinyl oral) + (1/MOE carpet dermal) + (1/MOE carpet oral))

ii. Intermediate-term Aggregate Assessment

The use patterns of the products and probability of co-occurrence must be considered when selecting scenarios for incorporation in the aggregate assessment. For example, homeowner painting activities occur only once or twice a year; therefore the probability of co-occurrence and the potential for exposure to residues from this use with other organic esters of phosphoric acid products on the same day is highly unlikely. Because most of the organic esters of phosphoric acid products are used as a materials preservative in the manufacturing of various materials and exposure to some of these materials (e.g., mattresses and vinyl tiles) can occur on a continuous basis, they were included in the aggregate assessments. It should be noted that based on the probability of co-occurrence of the uses that have intermediate-term exposure potential, it was determined that it was not necessary to conduct an adult intermediate-term aggregate assessment.

For children, the intermediate-term aggregate assessment includes dermal exposure to residues in mattresses, dermal exposure to residues in vinyl tiles, dermal exposures that result from use of carpet cleaner, incidental oral exposure to residues in vinyl tiles, and incidental oral exposure to residues that result from use of carpet cleaner.

The intermediate-term aggregate MOE for children is 91 and therefore of concern as it is below the target MOE of 100. Table 16 presents a summary of the child intermediate-term aggregate risk MOE.

Table 16. Summary of Child Intermediate-Term Aggregate Risk Estimates	
Exposure Scenario	**Total MOE[b] (Target MOE≥100)**
Dermal Exposure	
Mattress	110
Vinyl	1,500
Carpet Shampoo	2,100
Oral Exposure	
Vinyl	25,000
Carpet Shampoo	990
Total Aggregate Dose and MOE	**91**

a: Aggregate MOE = 1/((1/MOE mattress dermal) + (1/MOE vinyl dermal) + (1/MOE vinyl oral) + (1/MOE carpet dermal) + (1/MOE carpet oral))

6. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational risk is assessed for exposure at the time of application (termed "handler" exposure) and is assessed for exposure following application, or post-application exposure. Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate.

This occupational handler assessment only includes workers applying paint (brush/roller and airless sprayer) containing organic esters of phosphoric acid as a materials preservative. The "preservation of materials" refers to the scenario of a worker adding the preservative to the material being treated (paint, fabric, etc.). This can be applied using open pouring or closed delivery systems. This assessment does not include workers applying organic esters of phosphoric acid to the paint during manufacture because the active ingredient is applied via closed delivery system and worker exposure is believed to be minimal. Information on the use of closed systems for organic esters of phosphoric acid was provided by the registrant. Product labeling must be updated to ensure a closed delivery system is used when adding organic esters of phosphoric acid to paint during the manufacturing process. In addition, no occupational post-application exposures are assumed to occur and therefore, were not assessed. The representative scenarios selected for assessment were evaluated using maximum application rates as recommended on the product labels for organic esters of phosphoric acid.

Occupational risk for all of these potentially exposed populations is measured by an MOE which determines how close the occupational exposure comes to a NOAEL from toxicological studies. In the case for organic esters of phosphoric acid, the target MOE for identifying inhalation risks of concern is 100 and the target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000 (10x for inter-species extrapolation; 10x for intra-species variation; and 10x for route-to-route extrapolation). The Target MOE is 100 for dermal exposures for short- term exposures.

See the *Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic Acid Esters of Phosphoric Acid for the Reregistration Eligibility Decision (RED) Document,* dated 12/1/07 for a detailed explanation of the assumptions used in the assessment.

a. Occupational Toxicity

Table 2 provides a listing of the toxicological endpoints used in the occupational risk assessment for organic esters of phosphoric acid.

b. Occupational Handler Exposure

The Agency has determined that there is potential for dermal and inhalation worker exposure to organic esters of phosphoric acid when used as a materials preservative in paints. Only short-term exposure durations (1 to 30 days) were estimated because it was assumed that professional painters would not use organic esters of phosphoric acid- treated paint daily, and therefore exposures would occur on an intermittent basis. For this assessment, the application of preserved paint is considered to be representative of all organic esters of phosphoric acid material preservative uses. Both maximum and minimum application rates were used in the assessment of both dermal and inhalation exposure and risks.

There are no chemical-specific exposure data to assess professional handler exposures; therefore, to assess the handler risks, the Agency used surrogate unit exposure data from the Pesticide Handlers Exposure Database (PHED). The assessment was conducted using the Agency's standard assumptions for painters, wearing long pants, long sleeves and no gloves or respiratory protection. Short-term inhalation and dermal professional painter exposures were assessed and estimated risks are presented in Table 17.

c. Occupational Handler Risk Summary

Short-term exposure durations (1 to 30 days) were estimated because it was assumed that professional painters would not use organic esters of phosphoric acid-treated paint daily, and therefore exposures would occur on an intermittent basis. The target MOE for identifying inhalation risks of concern is 100 and the target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000 (10x for inter-species extrapolation; 10x for intra-species variation; and 10x for route-to-route extrapolation). An absorption factor of 100% was used (equivalency to oral absorption was assumed) for all inhalation and dermal exposure durations since the assessment is based on an oral endpoint. In cases where inhalation endpoints are set using oral toxicity data, as was done for organic esters of phosphoric acid, the Agency may need an inhalation toxicity study to confirm that the use of route-to-route extrapolation does not underestimate risk. The Agency determines the need for confirmatory inhalation data by evaluating the inhalation MOEs. For organic esters of phosphoric acid, if MOEs are greater then 100 but less then 1,000 confirmatory inhalation toxicity data may be required to account for the use of route-to-route extrapolation.

The short-term dermal and inhalation MOEs estimated for painters at the lower application rate are above the target MOEs of 100 and 1000 and not a concern. However, the short-term dermal MOEs estimated for painters at the maximum application rate are below the target MOE of 100 (MOE = 10 for paint brush use and MOE=5 for airless sprayer use) and therefore represent a concern. In addition, the short-term inhalation exposures resulting from the application of paint using an airless sprayer yield an MOE of 210. Although this MOE is above 100, it is below 1000 which indicates that an inhalation specific toxicity study may be warranted for this exposure scenario to confirm that the use of route-to-route extrapolation does not underestimate risk. For additional information regarding the short-term risks associated with occupational handlers, refer to Table 17.

Table 17. Organic Esters Of Phosphoric Acid Short-Term Professional Painter Exposures and MOEs

Exposure Scenario	Application Method	Application Rate[a]	Quantity Handled per day[b]	Dermal Unit Exposure (mg/lb a.i.)	Inhalation Unit Exposure (mg/lb a.i.)	Dermal Daily Dose (mg/kg/day)[c]	Inhalation Daily Dose (mg/kg/day)[c]	Dermal MOE[d] (Target MOE = 100)	Inhalation MOE[d] (Target MOE = 100)	Total MOE
Painting	Paint brush	0.1% a.i. by wt	50 lbs	180	0.28	0.13	0.00020	490	310,000	490
		5% a.i. by wt	50 lbs	180	0.28	6.43	0.010	**10**	6,300	**10**
	Airless sprayer	0.1% a.i. by wt	500 lbs	38	0.83	0.27	0.0059	230	11,000	230
		5% a.i. by wt	500 lbs	38	0.83	13.6	0.30	**5**	**210**	**5**

a Application rates are based on the minimum and maximum application rates determined from EPA registered labels (see Table 6.1).

b Amount handled per day values are standard EPA assumptions

c Daily dose (mg/kg/day) = [unit exposure (mg/lb a.i.) x application rate (% a.i. weight or lb a.i./gal) x quantity handled (lb/day or gal/day) x absorption factor (1.0 for dermal and inhalation)]/ Body weight (70 kg).

d MOE = NOAEL / Daily Dose. [Where short-term dermal and inhalation NOAEL = 62.5 mg/kg/day]. Target MOE = 100. Note: if inhalation MOE is below 1000 then an inhalation specific toxicity study may be warranted

e Total MOE = 1/((1/MOEdermal) + (1/MOEinhal))

d. Occupational Post-Application Exposure

No occupational post-application exposures are assumed to occur for organic esters of phosphoric acid; all post-application exposures from these uses are expected to occur in a residential setting. These exposure scenarios are assessed in the residential exposure assessment.

7. Human Incident Data

The Agency reviewed the following information for human poisoning incidents related to organic esters of phosphoric acid use: (1) OPP Incident Data System (IDS)- The Office of Pesticides Programs (OPP) Incident Data System contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992; (2)

California Department of Pesticide Regulation (1982-2004)- The California Department of Pesticide Regulation pesticide poisoning surveillance program consists of reports from physicians of illness suspected of being related to pesticide exposure since 1982; (3) National Pesticide Information Center (NPIC)- NPIC is a toll-free information service supported by OPP that provides a ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991; and (4) National Poison Control Centers (PCC) (1993-1996). No incidents involving organic esters of phosphoric acid were discovered.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for organic esters of phosphoric acid use sites and any associated uncertainties.

For detailed discussions of all aspects of the environmental risk assessment, see the *Environmental Fate Toxicology Disciplinary Chapter for the Issuance of the Reregistration Eligibility Decision Document*, dated November 27, 2007, and the *Ecological Hazard and Environmental Risk Assessment Chapter for the Organic Esters of Phosphoric Acid Reregistration Eligibility Decision (RED) Document* dated November 19, 2007.

1. Environmental Fate and Transport

The Agency considers the registered uses of organic esters of phosphoric acid to result in limited environmental exposure because of the nature of the mostly indoor use patterns. If a spill of organic esters of phosphoric acid were to occur in the environment, it is likely that terrestrial and aquatic organisms would be exposed to a mixture of these organic esters of phosphoric acid, the hydrolysis product ethylhexanol, phosphoric acid itself, salts of phosphoric acid (e.g., calcium phosphate), and the counter-ion cocoalkylimino-bis-ethanol. Organic esters of phosphoric acid are degraded primarily by the phosphatase enzymes associated with biological systems. However, some abiotic (chemical) hydrolysis may also occur. Ultimately, microbial hydrolysis to phosphoric acid is expected to be complete and association of the negatively-charged phosphate ion with cationic aquatic minerals will occur. Such salts of phosphoric acid are generally low in water solubility and may precipitate from solution depending on the pH, temperature, dissolved minerals, and other characteristics of the water body.

Mineral acids (e.g. phosphoric acid) pose a potential hazard to the aquatic environment not because of inherent toxicity but instead due to their ability to change the pH of receiving waters and create eutrophication. The pH is an important factor in the chemical and biological systems of natural waters, and the extent of pH change will depend on the buffering capacity of the water, sediment system, the magnitude of the spill, and the characteristics of the receiving water body (e.g. size, depth, flushing rate). In addition, eutrophication from sudden additions of plant nutrients such as phosphorus can result in rapid algal and aquatic plant growth in water bodies and cause oxygen shortages which can kill aquatic animals.

2. Ecological Risk

a. Environmental Toxicity

The ecological risk assessment integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. Organic esters of

phosphoric acid demonstrate relatively no toxicity to birds, low acute toxicity to freshwater fish, and relatively no toxicity to freshwater aquatic invertebrates.

Avian Species
No avian oral toxicity studies were found in the Agency's files for organic esters of phosphoric acid; however, an avian dietary study using an end use product was used to satisfy this data requirement.

Mammalian Species
Organic esters of phosphoric acid exhibit low acute oral toxicity (Toxicity Category IV); low acute dermal toxicity (Toxicity Category IV); and moderate acute inhalation toxicity (Toxicity Category III) based on the results of mammalian studies conducted to meet human toxicity data requirements. Organic esters of phosphoric acid are classified as mildly irritating to the eye (Toxicity Category III). For dermal irritation, organic esters of phosphoric acid are a low irritant (Toxicity Category IV) and are not classified as a dermal sensitizer.

Non-target Insect, Honeybees
Honeybee testing is not required for the currently registered uses of organic esters of phosphoric acid. Honeybees should not be exposed to organic esters of phosphoric acid because of the use patterns of this pesticide. Therefore, the honeybee LD_{50} test is not required.

Aquatic Organisms
No freshwater fish acute toxicity studies were found in the Agency's files for organic esters of phosphoric acid, however, two freshwater fish acute toxicity studies using an end use product were used to satisfy this data requirement. Early life stage testing in fish is not required for the currently registered uses of organic esters of phosphoric acid. No acute freshwater invertebrate studies were found in the Agency's files for organic esters of phosphoric acid, however, a freshwater invertebrate study using an end use product were used to satisfy this data requirement. Chronic freshwater invertebrate testing is not required for the currently registered uses of organic esters of phosphoric acid.

Toxicity testing with estuarine and marine organisms is not required for the currently registered uses of organic esters of phosphoric acid.

Plants
Toxicity testing with terrestrial and aquatic plants is not needed for the currently registered uses of organic esters of phosphoric acid.

A summary of the Acute Toxicity of organic esters of phosphoric acid to terrestrial and aquatic organisms is presented in Table 18.

Table 18. Acute Toxicity of Organic Esters of Phosphoric Acid to Terrestrial and Aquatic Organisms					
Species	**Chemical, % active ingredient (AI)**	**Endpoint**	**Toxicity Category (TGAI)**	**Satisfies Guidelines/ Comments**	**MRID**
Birds					
Bobwhite quail (*Colinus virginianus)*	Phosphoric Acid 48%	LC_{50} (diet) = >5620 NOAEC = 5620	Relatively nontoxic	Yes (core for formulated product) - 8-day test duration - 10 days of age	43909003
Freshwater Fish					
Bluegill sunfish (*Lepomis macrochirus)*	Phosphoric Acid 48%	LC_{50} = 60 (43-72) NOEC = 25	Slightly toxic	Yes (core for formulated product) - 96-hr test duration - static test system	43909005
Rainbow trout (*Oncorhynchus mykiss*)	Phosphoric Acid 48%	LC_{50} = 87 (74-123) NOEC = 26	Slightly toxic	Yes (core for formulated product) - 96-hr test duration - static test system	43909006
Freshwater Invertebrates					
Waterflea (*Daphnia magna)*	Phosphoric Acid 48%	EC_{50} = 105 (72-121) NOEC = 25	Relatively Nontoxic	Yes (core for formulated) - 48-hr test duration - static test system	43909007

b. Ecological Exposure and Risk

The Agency considers the registered uses of organic esters of phosphoric acid ones which result in limited environmental exposure. For these types of scenarios the

Agency performs ecological hazard and environmental labeling assessments and requires the submission of three ecological effects studies: avian acute oral LD_{50}, acute freshwater fish LC_{50}, and acute freshwater aquatic invertebrate EC_{50}.

Although there are no ecotoxicity data on the organic esters of phosphoric acid, if a spill of these organic esters were to occur in the environment, it is likely that terrestrial and aquatic organisms would be exposed to a mixture of organic esters of phosphoric acid, phosphoric acid, and salts of phosphoric acid (e.g., calcium phosphate). Further, considering that there are ecotoxicity data available for phosphoric acid, additional testing with the organic esters would not provide any additional pertinent information and is not required. There are adequate data available to determine the labeling for the organic esters by utilizing the data available for the mineral acid, phosphoric acid.

However, it should be noted that mineral acids such as phosphoric acid pose a potential hazard to the aquatic environment not because of inherent toxicity but instead due to their ability to change the pH of receiving waters and create eutrophication. The pH is an important factor in the chemical and biological systems of natural waters. In addition, eutrophication from sudden additions of plant nutrients such as phosphorus can lead to rapid algal and aquatic plant growth in water bodies and cause oxygen shortages which can kill aquatic animals. Sufficient exposure to mineral acids to significantly change the pH and cause eutrophication is harmful to aquatic species and such exposure should be avoided whenever possible.

3. Risk to Listed Species

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either

direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency – Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). The organic esters of phosphoric acid are registered for use patterns that are expected to have little to no environmental exposure. Chemicals in these categories do not undergo a full screening-level risk assessment.

The organic esters of phosphoric acid are mostly used indoors as fungicides, disinfectants, bacteriostats and microbicides/microbistats for materials preservation. This preliminary analysis does not indicate whether there is a potential for organic esters of phosphoric acid uses to overlap with listed species and whether a more refined assessment is warranted, to include direct, indirect, and habitat effects. The more refined assessment should involve clear delineation of the action area associated with proposed use of organic esters of phosphoric acid and best available information on the temporal and spatial co-location of listed species with respect to the action area. This analysis has not been conducted for this assessment. The Agency expects minimal environmental exposure from the registered use patterns; however an endangered species effect determination will not be made at this time.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing organic esters of phosphoric acid as an active ingredient. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of all supported products containing organic esters of phosphoric acid.

The Agency has completed its assessment of the residential, occupational, and ecological risks associated with the use of pesticide products containing the active ingredient organic esters of phosphoric acid. The Agency has determined that all organic esters of phosphoric acid-containing products are eligible for reregistration provided that: 1) all risk mitigation measures are implemented; 2) current data gaps and confirmatory data needs are addressed; and 3) label amendments are made as described in Section V. Appendix A summarizes the uses of organic esters of phosphoric acid that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of organic esters of phosphoric acid and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of organic esters of phosphoric acid, the Agency has determined that organic esters of phosphoric acid products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement the risk mitigation measures, submit confirmatory data as well as make the label changes identified in this document, the Agency may take regulatory action to address the risk concerns from the use of organic esters of phosphoric acid. If all changes outlined in this document are fully complied with, then no risks of concern exist for the registered uses of organic esters of phosphoric acid and the purposes of this determination. Once an endangered species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decision for organic esters of phosphoric acid. EPA released its preliminary risk assessment for organic esters of phosphoric acid for public comment on January 16, 2008. The Agency received a comment from the registrant during the 60-day public comment period, which closed on March 16, 2008. The comment was testimonial in nature, discussing the history of use for organic esters of phosphoric acid.

C. Regulatory Rationale

The Agency has determined that organic esters of phosphoric acid are eligible for reregistration provided that risk mitigation measures are implemented as outlined in this document, additional required data confirm this decision and label changes are made accordingly. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V. of this document.

1. Human Health Risk Management

a. Dietary (food) and Drinking Water Risk Mitigation

Based on the use patterns of organic esters of phosphoric acid, it is expected that there will not be any dietary or drinking water exposure. Therefore, neither dietary nor drinking water assessments were conducted. Furthermore, since these uses occur in an indoor environment, it is not expected that organic esters of phosphoric acid will impact any source of drinking water.

b. Residential Risk Mitigation

i. Handler Risk Mitigation

Residential handler risks were calculated for the short-term duration (1-30 days) because it best represents most homeowner applications. All residential handler risks were not of concern except for the:

- Short-term dermal MOE estimated for painters using a paint brush at the maximum application rate; MOE = 19
- Short-term dermal MOE estimated for painters using an airless sprayer at the maximum application rate; MOE = 7
- Short-term inhalation MOE estimated for painters using an airless sprayer at the maximum application rate; MOE = 700. The target MOE for identifying inhalation risks of concern is 100 and the target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000 (10x for inter-species extrapolation; 10x for intra-species variation; and 10x for route-to-route extrapolation), indicating that an inhalation specific toxicity study may be warranted for this exposure scenario.

In order to mitigate these risks of concern, the registrant must reduce the maximum application rate in paint from 5% to 0.25%.

Please note: At this time, there are no available mitigation measures other than reducing the application rate for the risks of concern associated with organic esters of phosphoric acid. However, the registrant believes that additional data will enable the Agency to refine its risk assessment and has proposed conducting and submitting the following studies:

1. an *in vitro* dermal absorption study; and
2. migration/transferable residue studies for the mattress, textile/clothing and carpet/floor shampoo use

Protocols will be submitted to the Agency for approval prior to conducting these studies. These studies will not be completed in time for inclusion in this RED. Once the data have been received and reviewed, the Agency may revise its human health risk assessment if appropriate. If the results of the revised risk assessment indicate that the risks are not of concern at higher application rates, the Agency will reconsider the risk mitigation measures stipulated in this RED. These studies must be received by the Agency no later than December 31, 2008 for consideration.

ii. Post-Application Risk Mitigation

Residential post-application risks were calculated for the short-term duration (1-30 days) for the textile/clothing use and for short-term duration and intermediate-term duration (1-6 months) for all other residential post-application risks. Although the short-term incidental oral MOE for children exposed to textiles/clothing was below the target MOE of 100 (MOE = 93), the Agency does not have a concern for this scenario because of the conservative nature of this assessment. The intermediate-term incidental oral MOE for children coming into contact with carpet cleaned with organic esters of phosphoric acid-treated shampoo was below the target of 100 (MOE =93). Again, due to the conservative nature of this assessment, the Agency does not have a concern for this scenario. All other residential handler risks were above the Agency's level of concern except for the:

- Short-term dermal MOE estimated for children coming into contact with mattress covers using a 100% residue transfer factor; MOE = 1
- Short-term dermal MOE estimated for children coming into contact with mattress covers using a 5% residue transfer factor; MOE = 23
- Short- and intermediate-term dermal MOE estimated for adults coming into contact with mattress covers using a 100% residue transfer factor; MOE = 2
- Short- and intermediate-term dermal MOE estimated for adults coming into contact with mattress covers using a 5% residue transfer factor; MOE = 38
- Short-term incidental oral MOE for children coming into contact with carpet cleaned with treated shampoo using a 100% residue transfer factor; MOE = 44
- Short-term dermal MOE for children exposed to textiles/clothing using a 100% residue transfer factor; MOE = <1
- Short-term dermal MOE for children exposed to textiles/clothing using a 5% residue transfer factor; MOE = 17
- Short-term dermal MOE for adults exposed to textiles/clothing using a 100% residue transfer factor; MOE = 1
- Short-term dermal MOE for adults exposed to textiles/clothing using a 5% transfer factor: MOE = 26

In order to mitigate these risks, the Agency has determined that the following is needed for reregistration eligibility:

1. Mattress Use (this use is inclusive of textiles and vinyl upholstery impregnated/treated with the active ingredient during the manufacturing process and includes mattress ticking and mattress covers and all other mattress components):
    - The active ingredient must be reduced to from 5% to 1.1% so as to reach the target MOE of 100;
    - A residue transfer study must be conducted to confirm the Agency's assumption of a 5% transfer rate; and
    - If the residue transfer study indicates that the transfer rate is lower than 5% (the current rate being used in the assessment), then it may be possible for the registrant to increase the amount of active ingredient in these products as long as the target MOE of 100 is reached.

2. Carpet Cleaner Use:
    - A residue transfer study must be conducted to confirm the 5% residue transfer rate used in the assessment

3. Textile Use:
    - The active ingredient must be reduced to from 2% to 0.34%; and
    - A residue transfer study must be conducted to confirm the 5% residue transfer rate used in the assessment.

Please note: At this time, there are no available mitigation measures other than reducing the application rate for the risks of concern associated with organic esters of phosphoric acid. However, the registrant believes that additional data will enable the Agency to refine its risk assessment by conducting an *in vitro* dermal absorption study and migration/transferable residue studies for the mattress, textile/clothing and carpet/floor shampoo use. Once the data have been received and reviewed, the Agency may revise its human health risk assessment if appropriate. If the results of the revised risk assessment indicate that the risks are not of concern at higher application rates, the Agency will reconsider the risk mitigation measures stipulated in this RED.

iii. Aggregate Risk

The mitigation measures outlined above for residential risks will also adequately address the aggregate risks of concern identified in this document.

c. Occupational Risk Mitigation

i. Handler Mitigation

There are two types of occupational handler exposures for the use of organic esters of phosphoric acid as a materials preservative. Based on information provided by the registrant, organic esters of phosphoric acid are applied in a manufacturing facility via closed delivery systems. The Agency expects that occupational exposure for handlers in a facility where closed

systems are in place to be negligible or minimal assuming appropriate PPE is utilized. However, current labels do not specifically state that closed delivery systems are used. Therefore, all labels must be updated to state that closed delivery systems are required at manufacturing facilities.

The other exposures that occur in an occupational setting are short-term dermal and inhalation exposures to a painter using paint treated (preserved) with organic esters of phosphoric acid. Only short-term (1-30 days) inhalation and dermal professional painter exposures were assessed as it was assumed that professional painters would not use organic esters of phosphoric acid-treated paint daily and therefore, exposures would occur on an intermittent basis.

The results of the occupational risk assessment indicate that there are two risks of concern for dermal exposure to paint and one risk of concern for inhalation exposure to paint. The following are the occupational handler risks of concern:

- Short-term dermal MOE estimated for painters using a paint brush/roller at the maximum application rate; MOE = 10
- Short-term dermal MOE estimated for painters using an airless sprayer; MOE = 5
- Short-term inhalation MOE estimated for painters using an airless sprayer at the maximum application rate; MOE = 700. The target MOE for identifying inhalation risks of concern is 100 and the target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000 (10x for inter-species extrapolation; 10x for intra-species variation; and 10x for route-to-route extrapolation), indicating that an inhalation specific toxicity study is warranted for this exposure scenario.
- Short-term inhalation MOE for painters using an airless sprayer; MOE = 210. The target MOE for identifying inhalation risks of concern is 100 and the target MOE for identifying the need for confirmatory inhalation toxicity data is 1,000 (10x for inter-species extrapolation; 10x for intra-species variation; and 10x for route-to-route extrapolation). Since the short-term airless sprayer inhalation MOE is below 1,000 for organic esters of phosphoric acid, confirmatory inhalation data may be required.

The following measure is needed in order to mitigate these risks of concern:

- The active ingredient must be reduced from 5% to 0.25%

Please note: At this time, there are no available mitigation measures other than reducing the application rate for the risks of concern associated with organic esters of phosphoric acid. However, the registrant believes that additional data will enable the Agency to refine its risk assessment by conducting an *in vitro* dermal absorption study and migration/transferable residue studies for the mattress, textile/clothing and carpet/floor shampoo use. Once the data have been received and reviewed, the Agency may revise its human health risk assessment if appropriate. If the results of the revised risk assessment indicate that the risks are not of concern at higher application rates, the Agency will reconsider the risk mitigation measures stipulated in this RED.

ii. Post-Application Risk Mitigation

At this time, there are no post-application exposures for the occupational uses of organic esters of phosphoric acid; therefore, no mitigation measures are necessary.

2. Environmental Risk Management

The Agency considers the uses of organic esters of phosphoric acid assessed in this RED to be unlikely to result in any appreciable exposure to terrestrial or aquatic organisms. Therefore, no risk mitigation measures are required.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all manufacturing use products containing organic esters of phosphoric acid. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Listed Species Considerations

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a "no effect" determination. Although the Agency expects minimal environmental exposure based on current use patterns, an Endangered Species Effect Determination cannot be made at this time.

b. General Risk Mitigation

Organic esters of phosphoric acid end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing organic esters of phosphoric acid specific to federally listed species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all listed species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting listed species risk mitigation measures, the more stringent measure(s) should be adopted.

V. What Registrants Need to Do

The Agency has determined that organic esters of phosphoric acid are eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; (ii) label amendments are made; and (iii) risk mitigation measures identified in this document are adopted. To implement this decision, the registrant must amend their product labeling to incorporate the label statement set forth in the Label Changes Summary Table in Section B below (Table 20). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For organic esters of phosphoric acid technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call-in (DCI):

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

2. submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Heather Garvie at (703) 308-0034 with questions regarding generic reregistration.

By US mail:
Document Processing Desk
Heather Garvie
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Heather Garvie
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

For end-use products containing the active ingredient organic esters of phosphoric acid, the registrant needs to submit the following items for each product:

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. two copies of the confidential statement of formula (EPA Form 8570-4);

2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. five copies of the draft label incorporating all label amendments outlined in Table 13 of this document;

4. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

5. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

6. the product-specific data responding to the PDCI.

Please contact Heather Garvie at (703) 308-0034 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk
Heather Garvie
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

By express or courier service:
Document Processing Desk
Heather Garvie
Office of Pesticide Programs (7510P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of organic esters of phosphoric acid has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory data requirements. A generic data call-in (DCI) will be issued at a later date.

The risk assessment noted deficiencies in the toxicological database for organic esters of phosphoric acid. Therefore, the Agency is requiring the following confirmatory data to complete the hazard database and support the current uses: 1) a dermal sensitization study; and 2) an *in vivo* mammalian micronucleus test. These data are required for all uses of organic esters of phosphoric acid that are eligible for reregistration.

Residue transfer studies for textiles/clothing, mattress/mattress ticking and carpet/floor cleaners also need to be conducted if these uses are to be eligible for reregistration. The residue transfer studies will be used to confirm the Agency's assumption of a 5% transfer rate. For the textile use, this residue transfer study needs to be completed in addition to lowering the active ingredient to 0.34%.

For the mattress use, a residue transfer study needs to be conducted in addition to lowering the active ingredient to 1.1%. The residue transfer study will be used to confirm the Agency's assumption of a 5% transfer rate.

For the carpet cleaner use, a residue transfer study needs to be conducted to support the 5% transfer rate used in the assessment.

In order for the paint uses to be eligible for reregistration, the active ingredient must be reduced to 0.25%.

There are several data deficiencies associated with the residential handler and post-application exposure assessments. Surrogate dermal and inhalation unit exposure values were taken from the proprietary CMA and Pesticide Handler Exposure Database. These exposure data are of insufficient quality and therefore the Agency will require that confirmatory monitoring data be generated to support the values used in these assessments. Many of the use parameters (e.g., amount handled and duration of use) were based on professional judgments. Therefore, descriptions of human activities associated with the uses assessed are required as confirmatory.

The requested toxicology, residential and occupational studies are outlined in Table 19.

Table 19. Confirmatory Data Requirements for Reregistration of Organic Esters of Phosphoric Acid	
Guideline Study Name	**New OPPTS Guideline No.**
In Vivo Mammalian Micronucleus Test/Mammalian erythrocyte micronucleus test	870.5395
Dermal Sensitization Study	870.2600
Indoor Surface Residue Dissipation (Dermal Residue Transfer Studies for Textiles/Clothing, Mattress/Mattress Ticking and Carpet Shampoo/Cleaner)	875.2300
Dermal Indoor Exposure	875.1200
Inhalation Indoor Exposure	875.1400
Product Use Information	875.1700 875.2700
Description of Human Activity	875.2800
Data Reporting and Calculations	875.2900
Applicator Exposure Monitoring Data Reporting	875.1600
Conditional Data Requirements	
In Vitro Dermal Absorption Study[a]	870.7600
90-Day Dermal Toxicity Study in Rat	870.3250

[a]This study may become a requirement if the study is conducted and used to revise the risks
[b]This study may become a requirement pending the outcome of the *in vitro* dermal absorption study

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing-use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 20, Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data

meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. A product-specific data call-in, outlining data requirements, will be sent to registrants at a later date.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 20, Label Changes Summary Table.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," *Federal Register*, Volume 56, No. 123, June 26, 1991.

a. Label Changes Summary Table

In order to be eligible for reregistration, all product labels must be amended to incorporate the risk mitigation measures outlined in Section IV of the Organic Esters of Phosphoric Acid RED. The following table describes how language on the labels should be amended.

Table 20. Labeling Changes Summary Table

Description	Amended Labeling Language	Placement on Label
Environmental Hazards Statements Required by the RED and Agency Label Policies	"This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Precautionary Statements

Table 20. Labeling Changes Summary Table		
Add language stating that this a.i. is not to be used in the manufacture of toys	"This product is not to be incorporated into toys."	Directions for Use
Add *specific* application rates for the textile use (during a meeting on 11/7/07, the registrant indicated that the topical textile treatment rate is 0.75% - 2% a.i. by weight of fabric)	"The topical textile treatment rate is X for fabric weighing X."	Directions for Use
Closed Systems and PPE Language	"Closed systems (from sealed tote tanks to vats via metering pumps for liquid materials or hoppers for polymer bead materials) must be used when applying the active ingredient." "Appropriate PPE (long pants, long-sleeved shirts, and chemical resistant gloves) must be used when applying the active ingredient."	Directions for Use

Table 20. Labeling Changes Summary Table		
Application Rate Changes	"The application rate for textiles and vinyl upholstery that are impregnated/treated with the active ingredient during the manufacturing process (including mattresses, mattress ticking, mattress covers and all other mattress components) must not exceed 1.1%." "The application rate for carpet/floor cleaners treated with the active ingredient must not exceed 0.017%." "The application for textiles treated with the active ingredient must not exceed 0.34%." "The application for paint treated with the active ingredient must not exceed 0.25%."	Directions for Use
Clarify language on label for the carpet use to be specific to carpet backings and floor/carpet shampoo use		Directions for Use

VI. APPENDICES

Appendix A. Table of Representative Use Patterns for Organic Esters of Phosphoric Acid

Table of Representative Use Patterns for Organic Esters of Phosphoric Acid				
Use Site	**Formulation**	**Method of Application**	**Application Rate/ No. of applications** [a]	**Use Limitations**
Materials Preservative				
Treated Paints	43670-1	Brush/roller Airless Sprayer	0.1% - 5% a.i. by weight	None
Treated Carpet Cleaners	43670-1	Low pressure spray to simulate rug shampoo machine	0.0033 lb ai/gal and 6.5e-5 lb ai/gal (5% a.i. x 8.34 lb/gal x 1 oz product/gal water x 1 gal/128 oz = 0.0033 lb a.i./gal) [b] 0.1% - 5% a.i. by weight	None
Treated Vinyl floor	43670-1	N/A	5% a.i. by weight	None
Treated Textiles (clothing and linen)	43670-1	N/A	0.75% - 2% a.i. by weight [c]	None
Treated Mattresses	43670-1	N/A	1-2% a.i. by weight	None

a: Note that application rate is given in terms of end-use product, not active ingredient.
b: Note that during the SMART meeting (11/7/07), the registrant indicated that the treated carpet cleaner is diluted prior to use by the consumer at a rate of 1 oz product/ 1 gallon of water
c: Note that during the SMART meeting (11/7/07), the registrant indicated that the topical textile treatment rate is 0.75% - 2%ai by weight of fabric. This specific textile use rate needs to be indicated on the label.

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

Guide to Appendix B

Appendix B contains listing of data requirements which support the reregistration for active ingredients within case #4122 (organic esters of phosphoric acid) covered by this RED. It contains generic data requirements that apply to organic esters of phosphoric acid in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR part 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which are available from the National technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 4). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

(1) Agricultural premises and equipment
(2) Food handling/ storage establishment premises and equipment
(3) Commercial, institutional and industrial premises and equipment
(4) Residential and public access premises
(5) Medical premises and equipment
(6) Human water systems
(7) Materials preservatives
(8) Industrial processes and water systems
(9) Antifouling coatings
(10) Wood preservatives
(11) Swimming pools
(12) Aquatic areas

2. Bibliographic Citation (Column 5). If the Agency has acceptable data in its files, this column list the identify number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition		43265801
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process		43265801
830.1670	61-2b	Formation of Impurities		43265801
830.1700	62-1	Preliminary Analysis		43265801
830.1750	62-2	Certification of Limits		43265801
830.1800	62-3	Analytical Method		43265801
830.6302	63-2	Color		43265801
830.6303	63-3	Physical State		43265801
830.6304	63-4	Odor		43265801
830.7200	63-5	Melting Point		43265801
830.7220	63-6	Boiling Point		43265801
830.7300	63-7	Density		43265801
830.7840 830.7860	63-8	Solubility		43265801
830.7950	63-9	Vapor Pressure		43265801
830.7370	63-10	Dissociation Constant in Water		Not required

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)		43265801
830.7000	63-12	pH		43265801
830.6313	63-13	Stability		Not required
830.6314	63-14	Oxidizing/Reducing Action		Not required
830.6315	63-15	Flammability		43265801
830.6316	63-16	Explodability		43265801
830.6317	63-17	Storage Stability		43265801
830.7100	63-18	Viscosity		43265801
830.6319	63-19	Miscibility		43265801
830.6320	63-20	Corrosion Characteristics		43265801
830.6321	63-21	Dielectric breakdown voltage		43265801
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test		43909003
850.1075	72-1	Acute Freshwater Fish (bluegill)		43909005
850.1075	72-1	Acute Freshwater Fish (rainbow trout)		43909006
850.1010	72-2	Acute Freshwater Invertebrate (daphnia magna)		43909007
TOXICOLOGY				

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.1100	81-1	Acute Oral – Rat		42907901
870.1200	81-2	Acute Dermal – Rabbit		42907902
870.1300	81-3	Acute Inhalation – Rat		40423801; 41365401; 41365402
870.2400	81-4	Primary Eye Irritation – Rabbit		44858903
870.2500	81-5	Primary Dermal Irritation – Rabbit		44858904
870.2600	81-6	Dermal Sensitization		Data gap
870.3100	82-1a	90-Day Feeding-Rodent		41083601
870.3200	82-2	21/28-Day Dermal Toxicity – Rat		Not required if 90-day dermal toxicity study is conducted
870.3250	82-3	90-day Dermal Toxicity – Rodent		Conditionally required – see Table 19
870.3465	82-4	90-Day Inhalation – Rat		Not required; registrant may want to conduct this study to refine the risk assessment prior to the DCI being issued
870.3700a	83-3a	Developmental Toxicity – rodent		41151601
870.3700	83-3b	Teratogenicity – Rabbit		Not required for the current registered uses
870.3800	83-4	Reproduction and Fertility Effects - 2 Generation Repro		Not required for the current registered uses

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.4100	83-1a	Chronic Feeding Toxicity – Rodent		Not required for the current registered uses
	83-1b	Chronic Feeding Toxicity - Non-Rodent (dog)		Not required for the current registered uses
870.4200	83-2a	Oncogenicity – Rat		Not required for the current registered uses
	83-2b	Oncogenicity – Mouse		Not required for the current registered uses
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity		Not required for the current registered uses
870.5100	84-2	Bacterial reverse mutation test		40564601; 40564602
870.5300		In Vitro mammalian cell gene mutation test		Not required. The available *in vitro* mutagenicity data satisfied this requirement.
870.5265	84-2a	Gene Mutation – ames		40564601; 40564602
870.5385	84-2b	Structural Chromosome Aberration		40564603
870.5395	84-2	*In Vivo* mammalian micronucleus test /Mammalian erythrocyte micronucleus test		Data gap
870.5450		Rodent dominant lethal assay		Not required for the current registered uses
870.5900	84-2	Mammalian cytogenetics (sister chromatid exchange)- hamster		40564604

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
870.7485	85-1	General Metabolism		Not required for the current registered uses
870.7600	85-2	Dermal Absorption		Conditionally required – see Table 19
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2300	133-3	Indoor Surface Residue Dissipation (Dermal Residue Transfer Studies for Textiles/Clothing, Mattress/Mattress Ticking and Carpet Shampoo/Cleaner)		Data gap
875.1200	233	Dermal Indoor Exposure		Data gap – needed to replace CMA and PHED data
875.1400	234	Inhalation Indoor Exposure		Data gap - needed to replace CMA and PHED data
875.1600		Applicator Exposure Monitoring Data Reporting		Data gap – needed to replace CMA and PHED data
875.1700 875.2700		Product Use Information		Data gap
875.2800	133-1	Description of Human Activity		Data gap
875.2900	134	Data Reporting and Calculations		Data gap

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis		Not required

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room S-4400, One Potomac Yard, 2777 South Crystal Drive, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained the April 19, 2006 preliminary risk assessment and the related supporting science documents. EPA then considered comments on the risk assessment and revised the risk assessment and supporting chapters as necessary. The revised risk assessment will be posted in the docket at the same time as the RED.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site:

http://www.regulations.gov

These documents include:

- Organic Esters of Phosphoric Acid Preliminary Risk Assessment; Notice of Availability, 1/16/08.

Preliminary Risk Assessment and Supporting Science Documents (RED Supporting Documents):

- Organic Esters of Phosphoric Acid. Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document. PC Codes 111286, 129079, 129080, Case 4122. DP Barcode D347010. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). December 3, 2007, William J. Hazel, Ph.D., Chemist, Risk Assessor.

- Product Chemistry Chapter for the Organic Acid Esters of Phosphoric Acid Reregistration Eligibility Decision Document (RED). PC Codes 111286, 129079, 129080, Case 4122. Team II Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division. October 24, 2007, Talia Lindheimer, Chemist.

- Ecological Hazard and Environmental Risk Assessment Chapter for the Organic Esters of Phosphoric Acid Reregistration Eligibility Decision (RED) Document (Case No.: 4122), Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). November 19, 2007, Genevieve Angle, Biologist.

- Occupational and Residential Dietary and Non-dietary Exposure Assessments of Organic Acid Esters of Phosphoric Acid for the Reregistration Eligibility Decision (RED) Document. PC Codes 111286, 129079, 129080, Case 4122. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). December 1, 2007, Cassi Walls, Ph.D., Chemist.

- Organic Esters of Phosphoric Acid: Toxicology Disciplinary Chapter for the Issuance of the Reregistration Eligibility Decision (RED) Document. PC Codes 111286, 129079, 129080, Case 4122. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). November 27, 2007. Jenny J. Tao, Toxicologist.

- Organic Esters of Phosphoric Acid: Environmental Fate Disciplinary Chapter for the Issuance of the Reregistration Eligibility Decision (RED) Document. PC Codes 111286, 129079, 129080, Case 4122. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). November 27, 2007. James Breithaupt, Agronomist.

Revised Risk Assessment and Revised Supporting Science Documents (RED Supporting Documents):

- Organic Esters of Phosphoric Acid. Human Health and Ecological Effects Risk Assessments for the Reregistration Eligibility Decision (RED) Document. PC Codes 111286, 129079, 129080, Case 4122. DP Barcode D347010. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). March 8, 2008, William J. Hazel, Ph.D., Chemist, Risk Assessor.

- Organic Esters of Phosphoric Acid: Toxicology Disciplinary Chapter for the Issuance of the Reregistration Eligibility Decision (RED) Document. PC Codes 111286, 129079, 129080, Case 4122. Risk Assessment and Science Support Branch (RASSB) Antimicrobials Division (7510P). February 26, 2008. Jenny J. Tao, Toxicologist.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

MRID #	Citations
40423801	Newton, P. (1986) Four Hour Acute Liquid Aerosol Inhalation Toxicity Study in Rats of Intersept: Study No. 420-2344. Unpublished study prepared by American Biogenics Corp. 41 p. 27-Nov-1987
40564601	Lavelle, G. (1986) Gene Mutation Test on Intersept the Salmonella/ Microsomal Assay for Bacterial Mutagenic Activity of Compound A: Intersept (Pomostat 941) Lot No. K13508 RJ: Laboratory Project ID: 85-1704-15. Unpublished study prepared by Hill Top Biolabs, Inc. 18 p. 23-Mar-1988
40564602	Buehler, E. (1987) Gene Mutation Test on Intersept the Salmonella/ Microsomal Assay for Bacterial Mutagenic Activity of Intersept, Lot #2991: Laboratory Project ID: 87-0795-11. Unpublished study prepared by Hill Top Biolabs, Inc. 20 p. 23-Mar-1988
40564603	Murli, H. (1987) Mutagenicity Test on Intersept in an in vitro Cy- togenetic Assay Measuring Chromosomal Abberation Frequencies in Chinese Hamster Ovary (CHO) Cells: HLA Study No.: 9845-0-437. Unpublished study prepared by Hazelton Laboratories America, Inc. 27 p. 23-Mar-1988
40564604	Murli, H. (1987) Mutagenicity Test on Intersept in an in vitro Cy- togenetic Assay Measuring Sister Chromatid Exchange Frequencies in Chinese Hamster Ovary (CHO) Cells: HLA Study No.: 9845-0-438. Unpublished study prepared by Hazleton Laboratories America, Inc. 20 p. 23-Mar-1988
41083601	Pickersgill, N. (1989) Intersept: 90 Day (Dietary Administration) Sub-Chronic Toxicity Study in the Rat: Report No. 5843-640/2. Unpublished study prepared by Hazelton UK. 262 P. 03-May-1989
41151601	Morseth, S. (1989) Teratology Study with Intersept in Rats: Project ID: HLA Study No. 2535-100. Unpublished study prepared by Hazleton Laboratories America, Inc. 242 p. 30-Jun-1989
42907901	Harrod, K. (1993) Acute Oral Toxicity (Limit Test) in Rats of Portersept HVAC with Intersept Acrylic Primer/Finish, White 3830: Revised Final Report 1: Lab Project Number: 93-9025-21 (A): 2-1-1/03-09-90/REV 5. Unpublished study prepared by Hill Top Biolabs, Inc. 32 p.
42907902	Harrod, K. (1993) Acute Dermal Toxicity (Limit Test) in Rabbits of Portersept HVAC with Intersept Acrylic Primer/Finish, White 3830: Revised Final Report 1:

Lab Project Number: 93-9025-21 (B). Unpublished study prepared by Hill Top Biolabs, Inc. 49 p.

43265801 Bhatt, S. (1994) Product Chemistry, Portersept HVAC with Intersept Acrylic Primer/ Finish, White 3830. Unpublished study prepared by Courtaulds Coatings, Inc. 77 p.

43909003 Palmer, S.; Beavers, J. (1995) Divosan X-Tend: A Dietary LC50 Study with the Northern Bobwhite: (Final Report): Lab Project Number: 425-101. Unpublished study prepared by Wildlife International Ltd. 22 p.

43909005 Zelinka, E.; Drottar, K.; Swigert, J. (1996) Divosan X-Tend: A 96-Hour Static Acute Toxicity Test with the Bluegill (Lepomis macrochirus): Final Report: Lab Project Number: 425A-102. Unpublished study prepared by Wildlife International Ltd. 42 p.

43909006 Zelinka, E.; Drottar, K.; Swigert, J. (1996) Divosan X-Tend: A 96-Hour Static Acute Toxicity Test with the Rainbow Trout (Oncorhynchus mykiss): Final Report: Lab Project Number: 425A-101. Unpublished study prepared by Wildlife International Ltd. 44 p

43909007 Drottar, K.; Swigert, J. (1995) Divosan X-Tend: A 48-Hour Static Acute Toxicity Test with the Cladoceran (Daphnia magna): Final Report: Lab Project Number: 425A-103. Unpublished study prepared by Wildlife International Ltd. 42 p.

44858903 Moore, G. (1999) Primary Eye Irritation Study in Rabbits: Antimicrobial Drip Pad, 2%: Lab Project Number: 7217. Unpublished study prepared by Product Safety Labs. 15 p. {OPPTS 870.2400}

44858904 Moore, G. (1999) Primary Skin Irritation Study in Rabbits: Antimicrobial Drip Pad, 2%: Lab Project Number: 7218. Unpublished study prepared by Product Safety Labs. 15 p. {OPPTS 870.2500}

Other Supporting Documents

Fong, H.R. 2003. *An Overview of Closed System Use in California 2001-2002.* Report HS-1849. California Environmental Protection Agency, Department of Pesticide Regulation, Worker Health and Safety Branch. June 2003.

U.S. Environmental Protection Agency (US EPA). 1997a. Standard Operating Procedures (SOPs) for Residential Exposure Assessments. EPA Office of Pesticide ProgramsBHuman Health Effects Division (HED). December 18, 1997.

U.S. Environmental Protection Agency (US EPA). 1997b. Exposure Factors Handbook. Volume I-II. Office of Research and Development. Washington, D.C. EPA/600/P-95/002Fa.

U.S. Environmental Protection Agency (US EPA). 1998. PHED Surrogate Exposure Guide. Estimates of Worker Exposure from the Pesticide Handler Exposure Database Version 1.1. Washington, DC: U.S. Environmental Protection Agency.

U.S. Environmental Protection Agency (US EPA). 1999. Evaluation of Chemical Manufacturers Association Antimicrobial Exposure Assessment Study. Memorandum from Siroos Mostaghimi, Ph.D., USEPA, to Julie Fairfax.

U.S. Environmental Protection Agency (US EPA). 2001. HED Science Advisory Council for Exposure. Policy Update, November 12. Recommended Revisions to the Standard Operating Procedures (SOPs) for Residential Exposure Assessment, February 22, 2001.

Web References

HERA. 2003. Human and Environmental Risk Assessment, Guidance Document Methodology, April 22, 2002 (http://www.heraproject.com/files/Guidancedocument.pdf).

The Estimation Programs Interface (EPI) Suite. Windows based suite of physical/chemical properties and environmental estimation models developed by the US EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) and Syracuse Research Institute (SRC). http://www.epa.gov/opptintr/exposure/docs/EPISuitedl.htm

Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the Organic Esters of Phosphoric Acid RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G. Batching of Organic Esters of Phosphoric Acid Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency will complete the batching at a later date.

Appendix H. List of All Registrants Sent the Data Call-In

A list of registrants sent the data call-in will be posted at a later date.

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site: http://www.epa.gov/opprd001/forms/.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf

8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit
www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program—Storage and Disposal Statements

   b. 84-1 Clarification of Label Improvement Program

   c. 86-5 Standard Format for Data Submitted under FIFRA

   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

   b. EPA Form No. 8570-4, Confidential Statement of Formula

   c. EPA Form No. 8570-27, Formulator's Exemption Statement

   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.
To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.